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TITLE 8. DEPARTMENT OF HEALTH AND SENIOR SERVICES

CHAPTER 38. HEALTH MAINTENANCE ORGANIZATIONS

TABLE OF CONTENTS

SUBCHAP	PTER 1. SCOPE AND DEFINITIONS	1
8:38-1.1	Scope	
8:38-1.2	Definitions	1
SUBCHAP	PTER 2. ESTABLISHMENT OF HEALTH MAINTENANCE ORGANIZATIONS	5
8:38-2.1	Certificate of need and licensing	
8:38-2.2	Application for a new or amended certificate of authority	
8:38-2.3	Issuance of a certificate of authority	7
8:38-2.4	Comprehensive assessment reviews	
8:38-2.5	Denial of a certificate of authority	8
8:38-2.6	Amendment to an approved certificate of authority	8
8:38-2.7	Notice of changes in HMO operations	
8:38-2.8	Approval of a point of service (POS) plan	
8:38-2.9	Changes in ownership interests	10
8:38-2.10	,	
8:38-2.11	Registered agent	10
8:38-2.12	Examinations	11
8:38-2.13	Violations	
8:38-2.14	Enforcement remedies available	11
8:38-2.15	Hearings	12
SUBCHAP	PTER 3. GENERAL REQUIREMENTS	
8:38-3.1	Compliance with laws and rules	13
8:38-3.2	Nondiscriminatory enrollment practices	13
8:38-3.3	Open enrollment	13
8:38-3.4	Member contract termination	
8:38-3.5	Provider contract termination	14
8:38-3.6	Hearings for provider terminations	
8:38-3.7	Complaint and appeal system	
8:38-3.8	Submission of documents and data	
8:38-3.9	Provider application for participation and the review panel	17
SUBCHAP	PTER 4. MEDICAL DIRECTOR	19
8:38-4.1	Designation of a medical director	19
8:38-4.2	Medical director's responsibilities	
SUBCHAP	PTER 5. HEALTH CARE SERVICES	20
8:38-5.1	Provision of health care services	
8:38-5.2	Basic comprehensive health care services	
8:38-5.3	Emergency and urgent care services	
8:38-5.4	Supportive services	
8:38-5.5	Health promotion programs	
8:38-5.6	Wilm's tumor	
8:38-5.7	Health care services for prescribed drugs	22

SUBCHAR	PTER 6. PROVIDER NETWORK	23
8:38-6.1	Health care service network	23
8:38-6.2	Primary, specialty and ancillary providers	23
8:38-6.3	Institutional services	
SUBCHAF	PTER 7. CONTINUOUS QUALITY IMPROVEMENT	26
8:38-7.1	Continuous quality improvement program	
8:38-7.2	External quality audit	
8:38-7.3	Performance and outcome measures	
8:38-7.4	Healthcare Data Committee	28
SUBCHAF	PTER 8. UTILIZATION MANAGEMENT	29
0.00.04	Lier-reine and a second and a second	00
8:38-8.1	Utilization management program	
8:38-8.2	Utilization management staff availability	
8:38-8.3	Utilization management determinations	
8:38-8.4	Appeals of utilization management determinations	
8:38-8.5	Informal internal utilization management appeal process (Stage 1)	
8:38-8.6	Formal internal utilization management appeal process (Stage 2)	
8:38-8.7	External appeals process	
8:38-8.8	General requirements for independent utilization review organizations	
8:38-8.9	Department review of HMO actions on IURO recommendations	33
SUBCHAF		0.4
	CONSUMERS	34
8:38-9.1	Policies and procedures	34
SUBCHAF	PTER 10. MEDICAL RECORDS	36
	Policies and procedures	
	Confidentiality of medical records	
	Maintenance of medical records	
	Copies of medical records	
8:38-10.5	Medical record retention	36
SUBCHA	PTER 11. FINANCIAL STANDARDS AND REPORTING	37
8:38-11.1	Minimum net worth	37
8:38-11.2	Investments	
	Reserve liabilities	
	Minimum deposits	
	Plan for continuation of services upon declaration of insolvency	
8:38-11.6	Financial reporting requirements	
8:38-11.7	Reporting of compensation arrangements with health care providers involving incentive or disincentive programs	
8:38-11.8		
	(Reserved)	

SUBCHAF	PTER 12. REHABILITATION, CONSERVATION AND LIQUIDATION	45
	Rehabilitation, conservation and liquidation generally	
8:38-12.2	Alternate methodology for assuring continuation of services to HMO members	45
SUBCHAF	PTER 13. LICENSING OF REPRESENTATIVES AND ADVERTISING	47
8:38-13.1	General applicability of producer licensing requirements	47
8:38-13.2		
8:38-13.3	g ,	
8:38-13.4		
	Trade and claims practices and coordination of benefits	
	Penalties	
SUBCHAF	PTER 14. INDEMNITY BENEFITS OFFERED BY A HEALTH MAINTENANCE	
	ORGANIZATION	51
8:38-14.1		51
8:38-14.2	Requirement to offer a point of service contract	51
8:38-14.3	General standards	51
8:38-14.4	Out-of-network benefit restrictions under an HMO POS contract with a	
	reinsurance-type or group master policy arrangement	52
8:38-14.5	POS under a reinsurance-type contract arrangement	
	POS under a group health contract master policy arrangement	
	POS under a dual contract arrangement	
8:38-14.8		
	(Reserved)	
0.00 14.0	(1100011000)	
SUBCHAF	PTER 15. PROVIDER AGREEMENTS AND RISK TRANSFERENCE	56
8:38-15.1	Assumption of financial risk or risk-sharing	56
8:38-15.2	·	
8:38-15.3	Review and approval	
	Penalties	
SUBCHAF	PTER 16. (RESERVED)	59
SUBCHAF	PTER 17. PLAN DOCUMENTS FOR GROUP CONTRACTS	60
	Scope and applicability	
	General requirements	
	Terms and conditions for plan documents	
	Specific standards for required provisions	
	Standards for optional provisions	
8:38-17.6	Compliance	62

SUBCHAP	TER 18. DRUG FORMULARIES	. 63
	Development of formulary	
8:38-18.3	Distribution of formulary	. 64
8:38-18.4	Operative date	. 64 . 65
APPENDIX	((RESERVED)	. 66

SUBCHAPTER 1. SCOPE AND DEFINITIONS

8:38-1.1 Scope

- (a) The rules in this chapter were developed by the Commissioner of Health and Senior Services in collaboration with the Commissioner of Banking and Insurance and govern the establishment and operation of health maintenance organizations in New Jersey pursuant to the authority set forth in N.J.S.A. 26:2J-1 et seq. These rules are only applicable to managed care plans that constitute a health maintenance organization as defined herein and in N.J.S.A. 26:2J-1 et seq.
 - (b) The provisions of these rules shall apply, except where in conflict with:
- 1. Any individual contract issued by a health maintenance organization (HMO) to the extent that the contract is formulated in accordance with the provisions of the New Jersey Individual Health Coverage Program established pursuant to N.J.S.A. 17B:27A-1 et seq.; or
- 2. Any contract issued to a small employer by a HMO to the extent that the contract is formulated in accordance with the provisions of the New Jersey Small Employer Health Coverage Program established pursuant to N.J.S.A. 17B:27A-17 et seq.
- (c) The provisions of these rules shall apply to any services of the HMO which are subcontracted to other entities.
- (d) Nothing contained in these rules shall be construed to limit the authority of the Division of Medical Assistance and Health Services of the Department of Human Services to impose, in any contract to provide HMO services to New Jersey Medicaid recipients, standards that exceed those set forth in this chapter.

8:38-1.2 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

"Authorized payor" means a person licensed and authorized to transact business in this State as a health maintenance organization, an insurer doing a health insurance business, a hospital service corporation, a medical service corporation, a health services corporation, a dental service corporation, a dental plan organization or a fraternal benefit society.

"Basic comprehensive health care services" means the following services: preventive care, emergency care, inpatient and outpatient hospital and provider care, diagnostic laboratory and diagnostic and therapeutic radiological services and other services set forth in N.J.A.C. 8:38-5, including all services listed at N.J.A.C. 8:38-5.2.

"Capitation" means a fixed payment for the provision of medical services not based on frequency or severity of services or supplies provided.

"Carrier" means an insurer authorized to transact the business of health insurance & defined at N.J.S.A. 17B:17-4, a hospital service corporation authorized to transact business in accordance with N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to transact business in accordance with N.J.S.A. 17:48A-1 et seq., or a health service corporation transacting business in accordance with N.J.S.A. 17:48E-1 et seq.

"Claims" means a request for payment of charges for services rendered or supplies provided by a provider to a member.

"Commissioner" means the State Commissioner of Health and Senior Services or his or her designee.

"Commissioner of Banking and Insurance" means the Commissioner of the New Jersey Department of Banking and Insurance or his or her designee.

"Consumer Price Index" or "CPI" means the medical component of the Consumer Price Index for All Urban Consumers, as reported by the United States Department of Labor, shown as an average index for the New York-Northern New Jersey-Long Island region and the Philadelphia-Wilmington-Trenton region combined as published by the Commissioner of Banking and Insurance in the New Jersey Register.

"Continuous quality improvement" means an ongoing and systematic effort to measure, evaluate, and improve an organization's process to continually improve the quality of health care services provided to members.

"Contract holder" means an employer or organization which purchases a contract for services.

"Department" means the New Jersey Department of Health and Senior Services.

"Emergency" means a medical condition manifesting itself by acute symptoms of sufficient severity including, but not limited to, severe pain, psychiatric disturbances and/or symptoms of substance abuse such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; serious impairment to bodily functions; or serious dysfunction of a bodily organ or part. With respect to a pregnant woman who is having contractions, an emergency exists where: there is inadequate time to effect a safe transfer to another hospital before delivery; or the transfer may pose a threat to the health or safety of the woman or the unborn child.

"Evidence of coverage" means a statement of the essential features and services of the HMO coverage which is given to the subscriber by the HMO or by the group contract holder.

"External quality review organization (EQRO)" means an organization approved by the Department pursuant to this chapter to perform external quality audits of HMOs.

"Financial incentive arrangement" means a formal mechanism instituted by an HMO or a secondary contractor that exposes a provider, or group of providers, to risk or reward based upon meeting or failing to meet prescribed standards.

"Financial risk" means participation in financial gains or losses accruing pursuant to a contractual arrangement, based on aggregate measures of medical expenditures or utilization.

"Formulary" means a list of prescription medications that are preferred for use through the provision of differential benefits or other means.

"GAAP" means Generally Accepted Accounting Principles.

"Gatekeeper system" means a system in which a member is permitted to access service and/or obtain indemnity benefits for covered services only when the service is rendered by the member's primary care provider, or the member's access to services and/or benefits is approved by the primary care provider or the HMO, as specified under the HMO's contract with the subscriber or contractholder.

"Group health contract" means a contract, filed by or with the New Jersey Department of Banking and Insurance or the Small Employer Health Benefits Program Board of Directors, as appropriate, issued by a carrier to a group of persons for the provision of indemnity benefits for expenses for covered services incurred in preventing or treating acute or chronic injury or illness of members, as specified in the contract. The term "group health contract" shall not include any contract issued on a form which has been disapproved or withdrawn from filing by the Department of Banking and Insurance, or determined incomplete by the Small Employer Health Benefits Program Board of Directors, as appropriate.

"Health benefits plan" means a benefits plan which pays or provides hospital and medical expense benefits for covered services, and is delivered or issued for delivery in this State. Health benefits plan shall not include the following plans, policies or contracts: accident only, credit, disability, long-term care, CHAMPUS supplement coverage, coverage for Medicare services pursuant to a contract with the United States Government, Medicare supplement, coverage for Medicaid services pursuant to a contract with the State of New Jersey, coverage arising out of a workers' compensation or similar law, automobile medical payment insurance, personal injury protection insurance issued pursuant to P.L. 1972, c.70 (N.J.S.A. 39:6A-1 et seq.) or hospital confinement indemnity coverage.

"Health care expenditures" means the cost, on an incurred basis, of health care services and supplies rendered by a participating provider or a nonparticipating provider which are the responsibility of the HMO in accordance with the contracts the HMO has issued to contract holders.

"Health center" means a facility owned or leased by an HMO, used by members to receive medical and ancillary services including but not limited to: lab, radiology, and pharmacy.

"Health maintenance organization (HMO)" means any individual or entity that undertakes to provide or arrange for basic comprehensive health care services through an organized system that combines the delivery and financing of health care on a prepaid basis to members.

"Indemnity" means the payment of expenses, in whole or in part, as they are incurred by a member for the delivery of covered services, in which the level of payment for expenses incurred, and the charge made for the expenses incurred, is not negotiated between the health care provider and the HMO, and there is no contractual arrangement between the health care provider and the HMO holding the enrollee harmless for any amount of the expense not paid by the HMO. Payment of the expense may be made

directly to the health care provider upon assignment by the member, or the member may be reimbursed for the expense incurred.

"Independent utilization review organization (IURO)" means an independent organization, comprised of physicians and other health care professionals representative of the active practitioners in New Jersey, with which the Department contracts in accordance with N.J.A.C. 8:38-8.8 to conduct independent medical necessity or appropriateness of services appeal reviews brought by a member or provider on behalf of the member, with the member's consent.

"Insurer" means any insurance company authorized to transact the business of insurance in New Jersey."

"Managed hospital payment" means agreements between the HMO and a hospital under which the financial risk primarily related to the degree of utilization rather than to the cost of services is transferred to the hospital.

"Master policy" means the document issued by a carrier to an HMO evidencing coverage of the subscribers and members of the HMO, or a class of subscribers and members of the HMO, under a group health contract.

"Medicaid marketing representative" means any person who is registered as a limited insurance representative pursuant to N.J.S.A. 17:22A-16 and who is authorized to solicit, negotiate or effect contracts with Medicaid recipients as an agent for a Medicaid-contracting HMO, and performs no other service for the HMO that would otherwise require that person to be authorized and licensed as an insurance producer.

"Medical screening examination" means an examination and evaluation within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, performed by qualified personnel pursuant to requirements in N.J.A.C. 8:43G-12, which are necessary to determine whether or not an emergency medical condition exists.

"Member" means an individual who is enrolled in an HMO.

"Network" means all participating providers under contract or other agreement acceptable to the Department to furnish health care services to members of the HMO.

"Net worth" means the excess of the admitted assets over total liabilities of an HMO.

"Out-of-network covered services" means indemnity benefits for covered services rendered to an HMO member by someone other than the HMO's contracted health care providers.

"Participating provider" means a provider which, under contract or other arrangement acceptable to the Department with the HMO or with its contractor or subcontractor, in accordance with the provisions of this chapter, has agreed to provide health care services to members with an expectation of receiving payment, other than a copayment or deductible, directly or indirectly from the HMO.

"Person" means any natural or artificial person including, but not limited to, individuals, partnerships, associations, trusts, or corporations.

"Plan documents" mean contract, evidence of coverage, certificate, and member handbook, collectively.

"Point of service contract" means a contractual arrangement between an HMO and a member, subscriber or contract holder whereby the HMO makes provision for the rendering of covered services to its members through a network of health care providers as well as an out-of-network covered services option.

"Primary care provider (PCP)" means an individual participating provider who supervises, coordinates and provides initial and basic care to members and maintains continuity of care and meets the qualifications in N.J.A.C. 8:38- 6.2.

"Primary contractor" means a provider that agrees directly with an HMO to provide one or more services or supplies directly to an HMO's members.

"Provider" means a physician or other health care professional, hospital facility, or other person who is licensed or otherwise authorized to provide health care services or other benefits in the state or jurisdiction in which they are furnished.

"Reinsurance-type contract" means a contract between an insurer and an HMO whereby the insurer agrees to indemnify the HMO for all expenses incurred by the HMO's members under a POS contract for out-of-network covered services, and further, the insurer agrees that it will indemnify the HMO's members for expenses incurred for out-of-network covered services for the duration of the period for which premiums are or have been paid by the contract holders or subscribers to the HMO, should the HMO be placed into conservation, rehabilitation or liquidation.

"SAP" means Statutory Accounting Practices.

"Secondary contractor" means a person who agrees to arrange for the provision of one or more services or supplies for an HMO's members. A primary contractor may also be a secondary contractor when acting as a broker or administrator for the rendering of services or supplies that, in scope of licensure, type or quantity, the primary contractor (provider) alone could not offer directly to members.

"Secondary network" means a distinct delivery system developed by an HMO to be offered with one or more of its products in addition to, as an alternative to, or a substitute for, the delivery system(s) for which the HMO obtained its initial certificate of authority.

"Service area" means the geographic area for which the HMO has been issued a certificate of authority, in accordance with this chapter.

"Subscriber" means, in the case of a group contract, an individual whose employment or other status, except family status, is the basis for eligibility for enrollment in the health maintenance organization or, in the case of an individual contract, the person in whose name the contract is issued.

"Uncovered health care expenditures" means costs to the HMO for health care services that are the obligation of the HMO for which a member may be liable in the event of an HMO's insolvency and for which no alternative arrangements (that guarantee, insure or provide assumption by a person or organization other than the HMO for the provision of services or benefits) have been made that are acceptable to the Commissioners of Health and Senior Services and Banking and Insurance.

"Urgent care" means a non-life-threatening condition that requires care by a provider within 24 hours.

"Utilization management" means a system for reviewing the appropriate and efficient allocation of health care services under a health benefits plan according to specified guidelines in order to recommend or determine whether, or to what extent, a health care service given or proposed to be given to a member should or will be reimbursed, covered, paid for, or otherwise provided under the health benefits plan. The system may include: preadmission certification, the application of practice guidelines, continued stay review, discharge planning, preauthorization or ambulatory care procedures and retrospective review.

SUBCHAPTER 2. ESTABLISHMENT OF HEALTH MAINTENANCE ORGANIZATIONS

8:38-2.1 Certificate of need and licensing

Any health maintenance organization (HMO) which proposes the establishment and/or operation of a health care facility or any change in or expansion of a health care facility, or the institution of new health care services as defined in the Health Care Facilities Planning Act (N.J.S.A. 26:2H-1 et seq.) shall comply with all pertinent provisions of the Act, as amended and N.J.A.C. 8:33, Certificate of Need application and Renewal process, and all applicable health planning and licensing rules and regulations.

8:38-2.2 Application for a new or amended certificate of authority

(a) Any person, organization or corporation desiring to establish and/or operate an HMO shall apply to the Commissioner for a certificate of authority, pursuant to N.J.S.A. 26:2J-1 et seq. Applications for a certificate of authority may be obtained from:

New Jersey State Department of Health and Senior Services
Office of Managed Care
PO Box 360
Trenton, NJ 08625-0360

or

New Jersey Department of Banking and Insurance
Managed Care Bureau
Life and Health Division
20 West State Street
PO Box 325
Trenton, NJ 08625-0325

- 1. Two copies of the entire application shall be submitted to the Department at the above address;
- 2. One copy of the entire application (excluding signed provider agreement pages) shall be submitted to the Department of Banking and Insurance at the above address; and
- 3. If the applicant proposes to be a Medicaid program participant, one copy of the application shall be submitted to:

New Jersey Department of Human Services
Office of Managed Health Care
Division of Medical Assistance and Health Services
PO Box 712
Trenton, NJ 08625-0712

- (b) The applicant shall submit to the Department a nonrefundable fee of \$100.00, or as specified in N.J.S.A. 26:2J-23, as may be amended, payable to the New Jersey Department of Health and Senior Services for the filing of an application for a certificate of authority as an HMO, or for any renewal or amendments thereto.
- (c) The application for a certificate of authority shall be deemed complete only when filed on forms prescribed by the Department and when accompanied by the following:
- 1. A copy of the basic organizational documents of the applicant such as the articles of incorporation, articles of association, partnership agreement, trust agreement or other applicable documents and all amendments thereto;
- 2. A copy of the bylaws, rules and policies or similar documents regulating the conduct of the internal affairs of the applicant;

- 3. A list of persons who are to be responsible for the conduct of the affairs of the HMO including names, addresses, official positions and a biographical affidavit for each person, including all officers and directors:
- 4. A specimen copy of the contract between the HMO and each participating provider, and an attestation by the HMO's CEO as to the execution of contracts by participating providers consistent with the information submitted by the HMO to demonstrate network adequacy and made in accordance with N.J.A.C. 8:38-15, including a description of any compensation program involving incentive or disincentive payment arrangements permitted under the laws of this State. As required by N.J.S.A. 26:2J-26, any copies of any contract made between the HMO and any provider, insurer, hospital or medical service corporation shall be considered confidential;
- i. Executed signature pages shall be made available to the Department or Department of Banking and Insurance upon request, but such documents shall otherwise remain confidential;
- 5. A copy of any merger or acquisition documents of the applicant or the applicant's parent if the merger or acquisition is with respect to the parent, management agreements for administrative services, and asset sale agreements.
 - 6. A copy of the form of evidence of coverage to be issued to the subscriber;
- 7. A copy of the form of the individual and group contract, if any, which is to be issued to subscribers and contract holders;
- 8. The most recent audited financial statements (or other documentation as specified by N.J.A.C. 8:38-11 for newly-formed applicants) showing the applicant's assets, liabilities, sources of financial support, a statement as to the sources of funding and all other financial requirements as delineated in N.J.A.C. 8:38-11;
 - 9. A description of the proposed method of marketing and financing;
- 10. A power of attorney duly executed by such applicant, if not domiciled in this State, appointing the Commissioner and his or her successors in office, and duly authorized designees, as the true and lawful attorney of such applicant in and for this State upon whom all lawful process in any legal action or proceeding against the HMO on a cause of action arising in this State may be served;
- 11. A description and map of the geographic area to be served, identified by county. If subareas of counties are to be proposed as boundaries of the service area, the map should also include zip codes;
- 12. Enrollment projections presented on a quarterly basis for the first three years of operation for each county or sub-area proposed as the service area. The enrollment projections should be accompanied by a description of the demographic characteristics of the population, including at least sex and age;
- 13. A description of the methods used by the HMO to facilitate access to services for culturally and linguistically diverse members;
 - 14. A description of the complaint and appeal procedures delineated in N.J.A.C. 8:38-3.6;
- 15. A description of the continuous quality improvement program delineated in N.J.A.C. 8:38-7;
- 16. A description of the utilization management program, including the process for appealing utilization management determinations delineated in N.J.A.C. 8:38-8;
- 17. A list of all participating providers by county, municipality and zip code, accompanied by maps of the service area identifying the location of these providers. This list shall include all PCPs, specialists, hospitals and ancillary providers. The list of PCPs and specialists shall include the individual's name, address and, if applicable, hospital affiliation;
- 18. The criteria regarding geographic accessibility and availability of its health care provider network and why the applicant believes these criteria meet or exceed the rules in this chapter. This shall be related to the applicant's enrollment projections, the access guidelines contained in this chapter, and the applicant's experience;
- 19. The criteria to be used to maintain the appropriate numbers and types of providers as enrollment increases in accordance with N.J.A.C. 8:38-6;
 - 20. The criteria used to ensure access to specialized services identified in N.J.A.C. 8:38-6;
- 21. A description of the method of informing affected members and providers of changes in the health care delivery network, as delineated in N.J.A.C. 8:38-3.5;

- 22. A description of the mechanism by which members and providers will be afforded an opportunity to participate in matters of policy and operation through establishment of advisory panels, by the use of advisory referendum on major policy decisions, or through the use of other mechanisms;
- 23. A statement from the applicant attesting that it or any affiliated entity operating as an HMO or regulated health insurance business has been in substantial compliance with all applicable state and Federal regulations for the last 12 months in any state in which approval to operate has been granted by the official state licensing and/or certification agency. A description and explanation of any enforcement action or settlement thereof affecting the HMO or its affiliate must be submitted including and not limited to fines, suspension of marketing, or revocation of a license or certificate to do business. The Commissioner may request further information from the applicant or from the official state or Federal agency to determine compliance; and
- 24. Such other information as the Commissioner or the Commissioner of Banking and Insurance may require on a case by case basis from a specific applicant, to make the determination required by N.J.S.A. 26:2J-4.

8:38-2.3 Issuance of a certificate of authority

- (a) A certificate of authority to establish and operate an HMO to service commercial enrollees shall be issued upon approval of the Commissioner and the Commissioner of Banking and Insurance.
- (b) A certificate of authority to establish and operate an HMO to service both Medicaid and commercial enrollees shall not be approved for purposes of serving Medicaid enrollees until such time that the Commissioner has received and considered the recommendation of the Department of Human Services, Division of Medical Assistance and Health Services on the applicant's compliance with the State and Federal requirements of a contract between the applicant and the Department of Human Services.
- (c) Issuance of a certificate of authority shall be granted upon demonstration of compliance, to the satisfaction of the Commissioner of Health and Senior Services and Commissioner of Banking and Insurance, with these rules and the requirements in N.J.S.A. 26:2J-1 et seq.
- (d) Prior to issuance of a certificate of authority, a preoperational audit shall be conducted by the Departments of Health and Senior Services, Banking and Insurance and/or Human Services to evaluate the HMO's ability to perform essential functions including, but not limited to, claims processing, utilization management and quality assurance protocols, adequacy of accounting and information systems, operational and financial controls, and network adequacy. The applicant shall bear all reasonable costs associated with conducting the preoperational audit, including, but not limited to, outside consultant and subcontractor fees.

8:38-2.4 Comprehensive assessment reviews

- (a) After issuance of a certificate of authority, the HMO shall undergo a comprehensive assessment review by the Department on a triennial basis.
- (b) The comprehensive assessment review conducted by the Department may include an on-site review and shall be based upon the Department's review of the following:
- 1. A filing of information by the HMO of any substantial change to operations identified in N.J.A.C. 8:38-2.7 not previously filed with the Department. This filing shall not require the submission of any documents previously filed with the Department, if such documents have remained valid and unchanged since their original filing;
 - 2. The results of the HMO's external quality audit, as required at N.J.A.C. 8:38-7.2;
- 3. A statement from the HMO attesting that it or any affiliate certified or licensed as an HMO or health insuror has been in substantial compliance with all applicable state and Federal rules and/or regulations for the last 12 months in any other state in which it has been approved to do business; and
- 4. All network adequacy, utilization management, continuous quality improvement, performance and outcome measurements or other data or information provided for in this chapter.
- (c) The comprehensive assessment review required at (b) above shall be conducted by the Department in accordance with the following schedule:
- 1. For HMOs with a valid certificate of authority issued between January 1, 1973 and December 31, 1985, the first review shall be conducted in the year beginning January 1, 1997, no more than 180 days and no less than 90 days prior to the anniversary date of original issuance;

- 2. For HMOs with a valid certificate of authority issued between January 1, 1986 and December 31, 1994, the first review shall be conducted in the year beginning January 1, 1998, no more than 180 days and no less than 90 days prior to the anniversary date of original issuance;
- 3. For HMOs with a valid certificate of authority issued between January 1, 1995 and July 1, 1997, the first review shall be conducted in the year beginning January 1, 1999, no more than 180 days and no less than 90 days prior to the anniversary date of original issuance; and
- 4. For HMOs with a valid certificate of authority issued after July 1, 1997, reviews shall be conducted every third year, no more than 180 days and no less than 90 days prior to the anniversary date of issuance.
- (d) An HMO that does not demonstrate compliance with the requirements of this chapter based on the Department's findings resulting from the comprehensive assessment review may be subject to enforcement actions pursuant to N.J.A.C. 8:38-2.14. Notice of violations shall be provided, pursuant to N.J.A.C. 8:38-2.13 to the HMO. The Department may also issue a narrative assessment of HMO performance based upon the comprehensive assessment review and require a corrective action plan from the HMO. This report shall become public information in the manner specified in N.J.A.C. 8:38-2.13(d).

8:38-2.5 Denial of a certificate of authority

Subject to the provisions of N.J.S.A. 26:2J-22, an application for a certificate of authority or amendment thereto may be denied if the Commissioner or the Commissioner of Banking and Insurance finds noncompliance with theses rules or any provision of N.J.S.A. 26:2J-1 et seq., or otherwise finds the HMO or other affiliated entity operating as an HMO or regulated health insurance business to be in violation of any other applicable New Jersey, other State or Federal law where these violations have resulted in an enforcement action, and the applicant owned, operated, or managed in whole or in part, the HMO which was the subject of the action during the 12 month period preceding the filing of the application.

8:38-2.6 Amendment to an approved certificate of authority

- (a) After issuance of a certificate of authority, any HMO which proposes to expand or reduce its service area, change the operational model of its health care delivery system, subcontract its complaint and appeal process, quality improvement, utilization management functions, credentialing, marketing, claims processing, or network management, engage in a transaction that results in any person having ownership of 10 percent or greater control of the HMO, or initiate a contract with Medicaid and/or Medicare shall be subject to the approval of the Commissioner and the Commissioner of Banking and Insurance for an amendment to the HMO's certificate of authority. Actions that shall require an amendment include, but are not limited to:
- 1. A change in the operational model of the health care delivery system, including, but not limited to:
 - i. A group model converting to or adding an individual practice association (IPA); or
- ii. An IPA model converting to or adding a group model, including establishment of the initial health center in any service area.
- 2. A change in the service area or sub-area, including adding or deleting a county or counties or sub-areas of a county (by zip code area); or
 - 3. A change in the enrollment of the HMO to include Medicaid or Medicare recipients.
 - (b) For purposes of this section, the following words and terms shall have the following meanings:

"Group model" means the HMO organizational model in which the HMO contracts with health care providers to serve only its members in a health center(s) owned or leased by the HMO.

"Individual practice association (IPA) model" means the HMO organizational model in which the HMO contracts with health care providers to serve its enrollees in their private offices.

(c) The HMO shall apply to the Departments of Health and Senior Services and Banking and Insurance to amend the certificate of authority and shall submit complete supporting documentation at least 60 business days prior to the planned implementation of the change. If the HMO is expanding its enrollment to include Medicaid enrollees, the HMO shall also submit a copy of the application to the Department of Human Services.

- (d) Neither HMOs nor carriers shall restrict utilization of any HMO's network or offer any alternative or substitute network of providers, whether or not the providers are or are not within an approved network of the HMO or carrier (for the purpose of offering rate differentials or for any other purpose) until the network restriction or alternative or substitute network is approved by the Department as a stand-alone secondary network adequate for the purposes intended.
- 1. HMOs shall submit requests for approval of secondary networks, and shall clearly identify the purpose of every secondary network. An application for modification of a certificate of authority shall include the following:
- i. A specimen copy of every form of a contract between the HMO and all providers to be included in the secondary network, with a statement as to whether the contract was previously approved for use with the HMO's standard network;
- ii. A specimen copy of the form of the individual and group contract and evidence of coverage, if any, which is to be issued to employers, unions, trustees or other organizations pursuant to utilization of the secondary network, with a statement as to whether the contract was previously approved for use with the HMO's standard network;
- iii. A description of the proposed method of marketing and financing of the secondary network:
- iv. A description and map of the geographic area to be served by the secondary network identified by county or zip codes, if sub-areas of counties are to be proposed as boundaries of the service area;
- v. Enrollment projections presented on a quarterly basis for the first three years of operation for each county or sub-area proposed as the service area, including a description of the demographic characteristics of the population by at least gender and age;
- vi. A list of providers under the proposed secondary network by county, municipality and zip code, accompanied by maps of the service area identifying the location of these providers, specialists, hospitals and ancillary providers, if any, including the name, address and hospital affiliation of every provider, as applicable;
 - vii. The proposed rates for the secondary network; and
- viii. Such other information as the Commissioner or the Commissioner of Banking and Insurance may require of a specific applicant to determine that a modification of the certificate of authority is appropriate.
- 2. The Commissioner shall approve an amendment for a secondary network based upon a determination that the secondary network is adequate to serve the purposes intended, as specified by the HMO, with respect to availability of services, product design (including integration with other networks established by the HMO, if integration will or may occur) and financial stability of the HMO. In making this determination, the criteria that apply to establishment of any network by an HMO shall apply to establishment of a secondary network.
- (e) In reviewing the proposed amendment to a certificate of authority, the Commissioner and Commissioner of Banking and Insurance shall determine whether the HMO has demonstrated compliance with all applicable rules of this chapter. The Commissioners shall also examine and evaluate the compliance record of the HMO for the period beginning 12 months prior to receipt of written notice, and may deny such application for a finding of non-compliance leading to an enforcement action pursuant to N.J.A.C. 8:38-2.13.
- (f) If the amendment to the certificate of authority is for the purpose of expanding the HMO's enrollment to include Medicaid enrollees, the amendment shall not be approved until such time that the Commissioner has received and considered the recommendation of the Department of Human Services, Division of Medical Assistance and Health Services on the HMO's compliance with the State and Federal requirements of execution of a contract between the HMO and the Department of Human Services.

8:38-2.7 Notice of changes in HMO operations

(a) Following issuance of a certificate of authority, the HMO shall notify the Departments of Health and Senior Services and Banking and Insurance, in writing, of any substantial change to items identified at N.J.A.C. 8:38- 2.2(c)1 through 24, at least 30 days prior to the date when such change is expected to occur. The Department shall deem such change approved within 30 days from the date of receipt of

notice of the change unless the Department notifies the HMO otherwise. Substantial changes include, but are not limited to:

- 1. Any change or reduction in the provider network that adversely impacts network adequacy requirements identified at N.J.A.C. 8:38-6;
- 2. The subcontracting of any major functions not specified at N.J.A.C. 8:38-2.6(a) to another entity;
- 3. The nonrenewal of a hospital provider's contract which shall be reported in accord with N.J.A.C. 8:38-3.5(b); and
- 4. The establishment of a new group health center in a county or service area that has previously received certificate of authority approval for initiation of group health center services in that area.

8:38-2.8 Approval of a point of service (POS) plan

In addition to the requirements set forth in N.J.A.C. 8:38-2.7, any HMO proposing to enter into an arrangement for the provision of out-of-network covered services to members shall also comply with the requirements delineated in N.J.A.C. 8:38-14.

8:38-2.9 Changes in ownership interests

Any change of control of the HMO shall be subject to review and approval by the Commissioner of Banking and Insurance pursuant to the New Jersey Insurance Holding Company Systems Act, N.J.S.A. 17:27A-1 et seq., and implementing rules, including N.J.A.C. 11:1-35.

8:38-2.10 Surrender of a certificate of authority

- (a) Except as the Holding Company Systems Act, N.J.S.A. 17:27A-1 et seq. and rules promulgated pursuant thereto may apply and require otherwise, in the event that an HMO voluntarily ceases operation, it shall provide at least 90 business days advance notice to all members, employers, providers and the Departments of Health and Senior Services and Banking and Insurance. The notice shall identify the storage location of medical records, where applicable, and procedures for obtaining copies of such records.
- (b) Every HMO intending to surrender a certificate of authority shall provide a plan at least 90 business days in advance of the surrender to the Department to assure continuity of coverage and medical care and assistance to members, as necessary, in accordance with N.J.A.C. 8:38-12.2.
- (c) Except as the Holding Company Systems Act, N.J.S.A. 17:27A-1 et seq. and rules promulgated pursuant thereto may apply and require otherwise, when the surrender is due to an acquisition or merger, the certificate of authority shall remain active and obligations of the surrendering HMO shall remain in effect until the termination notices and requirements of the IHC and SEH programs are met and all liabilities of the HMO surrendering its certificate of authority are assumed by the surviving entity, or are otherwise extinguished.

8:38-2.11 Registered agent

Each HMO shall maintain an office in New Jersey and provide the Department with the name and address of its registered agent or else a power of attorney duly executed by such applicant, if not domiciled in this State, appointing the Commissioner and his or her successors in office, and duly authorized designees, as the true and lawful attorney of such applicant in and for this State upon whom all lawful process in any legal action or proceeding against the HMO on a cause of action arising in this State may be served. The HMO shall assure in writing that it submits to New Jersey jurisdiction for all New Jersey laws and regulations and that it shall submit to inspections by Department of Health and Senior Services and/or Department of Banking and Insurance staff at any out of state site.

8:38-2.12 Examinations

- (a) The Department and the Department of Banking and Insurance may conduct an examination of the HMO annually, but in no case less than once every three years, concerning the quality of health care services and other affairs of the HMO, including providers with whom such organization has contracts, agreements, or other arrangements. This examination may include, but not be limited to, the review of documents, patient records, information required in N.J.A.C. 8:38- 3.6, and conferences with providers and members. The HMO shall be assessed an amount authorized at N.J.S.A. 26:2J-18, as may be amended, to offset the expenses of examination under this section. The fee shall be remitted within 90 days following the date of the assessment.
- (b) The Department shall incorporate the annual examination process as described above into the comprehensive assessment review process.
- (c) The Department may conduct special examinations at any time to ascertain whether the HMO is in compliance with this chapter and all applicable State and Federal statutes and regulations. A report of this examination shall be provided to the HMO within 30 business days of completion of the special examination. Any violations resulting from this examination shall be identified and responded to in accordance with N.J.A.C. 8:38-2.13.

8:38-2.13 Violations

- (a) A violation may be cited by the Commissioner of Health and Senior Services and/or Banking and Insurance or their designees upon determination that the HMO does not comply with the rules in this chapter and N.J.S.A. 26:2J-1 et seq.
- (b) At the conclusion of an examination, or within 30 business days thereafter, the Department shall provide the HMO with a written summary of violations of this chapter and any factual findings used as a basis to determine that a violation has occurred.
- (c) The Department or the Department of Banking and Insurance may require that the HMO submit a written plan of correction specifying how each violation that has been cited will be corrected along with the time frames for completion of each corrective action. A single plan of correction may address all events associated with a given violation. The plan of correction, where required, shall be submitted by the HMO within 20 business days of receipt of the notice of violations, or sooner, if the Commissioner determines that the violations jeopardize the safety of enrollees. The plan of correction shall be reviewed by the Department and shall be approved where the plan demonstrates to the satisfaction of the Department that compliance will be achieved within a reasonable time period. If the plan is not approved, the Departments of Health and Senior Services and Banking and Insurance may request that an amended plan of correction be submitted within five business days.
- (d) The summary of violations and the written plan of correction shall not be released as public information until such time that the Department has received the plan of correction or, in the event no plan of correction is submitted, 20 business days of receipt of the summary of violations by the HMO, whichever is sooner. Unless otherwise documented, the Department will presume receipt of the summary of violations by the HMO by the third business day if sent by regular mail.

8:38-2.14 Enforcement remedies available

- (a) The Commissioner may impose the following enforcement remedies against an HMO for violations of regulations in this chapter or other statutory requirements:
- 1. A monetary penalty may be imposed for each violation in an amount determined by the Commissioner, which shall be in amounts as authorized by N.J.S.A. 26:2J-24 (not less than \$250.00 and not greater than \$10,000 for each day that the carrier is in violation, based on the severity of the violation, as determined by the Commissioner on a case-by-case basis), as amended from time to time. The Department shall provide the HMO with reasonable notice in writing of the intent to levy the penalty, and a reasonable time, as determined by the Commissioner, within which to correct the violation. Any such penalty may be recovered in a summary proceeding pursuant to the Penalty Enforcement Law (N.J.S.A. 2A:58 et seq.);
- 2. Suspension of a certificate of authority pursuant to N.J.S.A. 26:2J-19, which may include the suspension of marketing and enrollment;

- 3. Revocation of a certificate of authority pursuant to N.J.S.A. 26:2J-19;
- 4. An order to cease and desist pursuant to N.J.S.A. 26:2J-24;
- 5. Institution of a proceeding to obtain injunctive relief pursuant to N.J.S.A. 26:2J-24;
- 6. Other remedies for violations of statutes, as provided by State or federal law.
- (b) The Commissioner shall serve notice to the HMO of any proposed enforcement remedy under this section, setting forth the specific violations, charges or reasons for the action. Such notice shall be served on the HMO or its registered agent in person or by certified mail.
- (c) The assessment of civil monetary penalties, or revocation of a certificate of authority, shall become effective 30 days after the date of mailing or the date on which such notice was personally served on an HMO, unless the HMO files with the Department a written answer to the charges and gives written notice to the Department of its desire for a hearing, in accordance with N.J.A.C. 8:38-2.15. In such cases, the HMO may request an abeyance of the enforcement remedy until an administrative hearing has been concluded and a final decision is rendered by the Commissioner. The Commissioner may grant the abeyance where he or she determines that such action would not endanger the health, safety, and welfare of HMO members. Hearings shall be conducted in accordance with N.J.A.C. 8:38-2.15.
- (d) Upon the imposition of an order to suspend marketing and enrollment, or following the suspension of a certificate of authority, the HMO shall not enroll any additional enrollees, except newborn children or other newly acquired dependents of existing enrollees.
- (e) Upon the revocation of the certificate of authority, the HMO shall notify all members and providers and follow procedures in N.J.S.A. 26:2J-19d.
- (f) The Commissioner or the Commissioner of Banking and Insurance may issue an order directing an HMO or a representative of an HMO to cease and desist from engaging in any act or practice in violation of the provisions of this chapter and N.J.S.A. 26:2J-1 et seq. Within 20 days after service of such an order, the HMO may request a hearing on the question of whether acts or practices in violation of this chapter and N.J.S.A. 26:2J-1 et seq. have occurred.
- (g) The Commissioner may institute a proceeding to obtain injunctive relief, in accordance with New Jersey Court Rules, if the Commissioner elects not to issue a cease and desist order, or in the event of non-compliance with a cease and desist order pursuant to N.J.S.A. 26:2J-24(d).

8:38-2.15 Hearings

- (a) Pursuant to N.J.S.A. 26:2J-22, if the Commissioner proposes to suspend, revoke, or deny a certificate of authority, or issues a cease and desist order, the Commissioner shall notify the HMO and the Commissioner of Banking and Insurance in writing, specifically stating the grounds for such denial, suspension, revocation, or order and fixing a time of at least 20 days thereafter for a hearing on the matter.
- (b) If the Commissioner levies a civil penalty, the HMO has a right to request a hearing on the matter, which must be filed within 20 days of receipt of the notice.
- (c) The hearing will be conducted through the Office of Administrative Law in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1.
- (d) After such hearing or upon failure of the HMO to request a hearing, the Commissioner shall make a final determination based on written findings and make such findings available to the HMO and the Commissioner of Banking and Insurance.
- (e) The recommendations and findings of the Commissioner of Banking and Insurance shall be conclusive and binding upon the Commissioner in relation to suspension, revocation, or denial of a certificate of authority when the matter concerns the following:
 - 1. Insurance business; and/or
 - 2. Requirements in N.J.A.C. 8:38-11 through 15.

SUBCHAPTER 3. GENERAL REQUIREMENTS

8:38-3.1 Compliance with laws and rules

- (a) The HMO shall comply with the provisions of the New Jersey Health Maintenance Organizations Act, N.J.S.A. 26:2J-1 et seq.
 - (b) The HMO shall comply with applicable Federal, state, and local laws, rules and regulations.

8:38-3.2 Nondiscriminatory enrollment practices

- (a) Except as provided in N.J.A.C. 8:38-3.4(a), an HMO shall not refuse to renew the coverage of a member covered under a contract for basic health care services, or alter the terms of, or cancel, an existing contract solely on the basis of the following:
 - 1. The health of the member:
 - 2. The age of the member;
 - 3. The sex of the member;
 - 4. The frequency of the member's use of the health care services of the HMO;
 - 5. The filing of a complaint or appeal by the member as permitted by these rules; or
- 6. Other reasons prohibited by the Trade Practices Act, N.J.S.A. 17B-30-1 et seq., or the New Jersey Law Against Discrimination, N.J.S.A. 10:5-1.1 et seq.
- (b) In accordance with N.J.S.A. 17B:48E-20, contracts of an HMO which provide coverage of a family member or dependents of a member shall also provide coverage to a newborn child of a member from the moment of birth until 31 days after the date of birth as if that child were enrolled, without additional premium for these 31 days. The coverage for newly-born children shall consist of coverage of at least injury or sickness, including the necessary care and treatment of medically diagnosed congenital defects and birth abnormalities.
- (c) Contracts of an HMO which provide coverage of a member but do not provide coverage for a family member or dependent of the member shall nevertheless provide for coverage of newborn children of the member from the moment of birth until 31 days after the date of birth as if that child were enrolled, unless the contracts are such as provide no dependent coverage whatsoever for the member's class. The coverage for newly-born children shall consist of coverage of at least injury or sickness, including the necessary care and treatment of medically diagnosed congenital defects and birth abnormalities, provided application and payment of the required premium are submitted to the HMO to include coverage for a newly-born child within 31 days from the date of birth. The services under this section must be authorized by the HMO.

8:38-3.3 Open enrollment

- (a) After an HMO has been in operation for 24 months, it shall have an annual open enrollment period for its group contracts for basic health care services of at least one month during which it accepts members up to the limits of its capacity, as determined by the HMO, in the order in which they apply for membership. Such requirement for annual open enrollment is not applicable to contracts executed pursuant to N.J.S.A. 17B:27A-18 and 19.
- (b) Notwithstanding (a) above, HMOs providing or arranging for basic health care services on a group contract basis may limit the open enrollment to all members of the group or groups covered by such contracts.
- (c) The HMO shall notify its subscribers in writing, both at the time of enrollment and through a notice in the promotional material which it distributes to prospective members, that, unless the member moves his or her place of residence outside of the HMO's designated service area, a person's choice of health benefits plan generally will determine his or her coverage until the next annual open enrollment period, regardless of the continued availability of a particular health care provider who contracts with the HMO.

8:38-3.4 Member contract termination

- (a) A member shall not have his or her membership in an HMO cancelled except for the following reasons:
- 1. Failure to pay the premiums and other applicable charges for such coverage, including copayment coinsurance and deductibles;
 - 2. Failure to abide by the rules and/or policies and procedures of the HMO;
- 3. Fraud or material misrepresentation affecting coverage, including misuse of a member identification card; or
- 4. The group of which the individual is a member is not renewed in accordance with the HMO's underwriting guidelines or is cancelled for failure to pay premiums.
- (b) Before a member's coverage can be terminated for (a)1 and 2 above, the member shall be given written notice of the violation and a reasonable opportunity to come into compliance. Following any decision to terminate a member's coverage, the HMO shall notify the member of his or her right to appeal such decision as set forth in N.J.A.C. 8:38-3.7.

8:38-3.5 Provider contract termination

- (a) The HMO shall establish a policy governing termination of health care professionals and other providers. The policy shall include at least:
- 1. Standards by which the HMO will provide notice to the provider of termination of his or her participation in the time and manner specified in the provider's contract.
- i. In instances in which the contract is terminated prior to the contract's renewal date, the HMO shall provide health care professionals with at least 90-days written notice of the termination, specifying the health care professional's right to a hearing before a panel appointed by the HMO.
- (1) The HMO shall provide in writing the reasons for the termination, if requested by the health care professional, within no more than 15 days of receipt of the request if the reason is not otherwise stated in the written notice of termination.
- ii. HMOs shall not be required to provide 90-days prior written notice and the opportunity for a hearing for terminations of health care professionals based on: nonrenewal of the contract, a determination of fraud, breach of contract by the health care professional, or the opinion of the HMO's medical director that the health care professional represents an imminent danger to a patient or the public health, safety and welfare.
- (1) An HMO that terminates a contract based on a determination of fraud shall report the fraud, with the basis for the determination of fraud, to the appropriate administrative agency (that is, the health care professional's licensing entity, such as the Board of Medical Examiners, the Board of Pharmacy, the Board of Chiropractic, and the Division of Criminal Justice).
- (2) An HMO that terminates a contract based on a determination that the health care professional represents an imminent danger to the patient or the public health, safety and welfare shall report the determination to the appropriate State licensing board, and reports to the State Board of Medical Examiners shall be subject to N.J.S.A. 45:9-19.5.
- 2. Methods by which the termination policy shall be made known to providers upon initial participation and at the time of renewal of the provider's contract.
- (b) HMOs shall provide written notification to each member at least 30 business days prior to the termination or withdrawal from the HMO's provider network of a member's PCP and any other physician or provider from which the member is currently receiving a course of treatment.
- 1. The 30-day prior notice to members may be waived in cases of immediate termination of a provider based on breach of contract by the provider, a determination of fraud, or where the HMO's medical director is of the opinion that the provider is an imminent danger to a patient or the public health, safety or welfare.
- (c) The HMO shall assure continued coverage of covered services at the contract price by a terminated health care professional for up to four months in cases where it is medically necessary for the member to continue treatment with the terminated health care professional except as set forth below.
- 1. In cases of the pregnancy of a member, medical necessity shall be deemed to have been demonstrated and coverage of services by the terminated health care professional shall continue to the postpartum evaluation of the member, up to six weeks after delivery.

- 2. In the case of care post-operative care, coverage of services by the terminated health care professional shall continue for a period of up to six months.
- 3. In the case of oncological treatment, coverage of services by the terminated health care professional shall continue for a period up to one year.
- 4. In the case of psychiatric treatment, coverage of services by the terminated health care professional shall continue for a period of up to one year.
- 5. The HMO is not required to continue coverage for services obtained through a terminated health care professional in those instances in which the health care professional has been terminated based upon: the opinion of the HMO's medical director that the health care professional is an imminent danger to a patient or the public health, safety and welfare, a determination of fraud, or a breach of contract by the health care professional, or the health care professional is the subject of disciplinary action by the State Board of Medical Examiners.
- 6. The determination as to the medical necessity of a member's continued treatment with a terminated health care professional shall be subject to the appeal procedures set forth at N.J.A.C. 8:38-8.5 through 8.7.
- (d) The HMO shall include in its agreements with providers, other than hospital providers, that, regardless of which party terminates the agreement, or the reasons for the termination, the HMO and the provider shall abide by the terms of the provider agreement, including reimbursement terms, for four months following the date of the termination, but the agreement may state that the provider has no obligation under the agreement to provide, and the HMO has no obligation to reimburse at the contracted rate, services which are not medically necessary to be provided by the provider on and after the 31st day following the date of termination.
- (e) In the event that a hospital's contract is not renewed, or is terminated by either party, the hospital and the HMO shall continue to abide by the terms of the most current contract for a period of four months from a severance date mutually agreed upon by both parties as required by N.J.S.A. 26:2J-11.1. In such an event, the HMO shall provide written notification within the first 15 business days of the four month extension to all health care providers with which it has contracted and members who reside in the county in which the hospital is located or in an adjacent county within the HMO's service area. The notice to members shall also advise them of available options with respect to their health care coverage.

8:38-3.6 Hearings for provider terminations

- (a) A health care professional shall have the right to request in writing a hearing within 10 business days following the date of receipt of notice of termination of the health care professional occurring prior to the date of termination from an HMO's network stated in the provider agreement.
- 1. A contract shall be deemed to have terminated, creating the right to a hearing, whenever a contract terminates on any date other than a designated renewal or anniversary date of the contract, except that no such right shall exist with respect to terminations described at N.J.A.C. 8:38-3.5(a)1ii.
- 2. If no renewal or anniversary date is specified in the contract, then the renewal or anniversary date shall be deemed to be the month and day in each calendar year on which the contract was originally signed by both parties, or become effective, whichever date is latest.
- (b) The HMO shall hold a hearing within 30 days following receipt of a written request for a hearing by a terminated health care professional before a panel appointed by the HMO.
 - 1. The panel shall consist of no less than three people.
- 2. At least one person on the panel shall be a clinical peer in the same or substantially similar discipline and specialty as the provider requesting the hearing.
- 3. The HMO shall not preclude the provider from being present at the hearing, nor shall the HMO preclude the provider from being represented by counsel at the hearing.
- (c) The panel shall render a decision on the matter in writing within 30 days of the close of the hearing unless the panel provides notice of a need for an extension for the rendering of its decisions to both the HMO and the health care professional prior to the date the panel's decision would otherwise be due.
- 1. The panel's decision shall set forth the relevant contract provisions and the facts upon which the HMO and the provider have relied at the hearing.

- 2. The panel shall recommend that the provider be terminated, reinstated or provisionally reinstated.
- 3. The panel shall specify its reasons for its recommendations, including the reasons for any conditions for provisional reinstatement.
- 4. The panel shall specify the conditions for provisional reinstatement, the duration of the conditions, and the consequences of a failure to meet the conditions.
- 5. In the event of reinstatement or provisional reinstatement, the panel shall specify the impact of the reinstatement upon the terms of duration of the contract at issue.
- (d) In the event that the panel recommends that the health care professional be terminated, the HMO shall then provide notice of the termination to members in accordance with N.J.A.C. 8:38-3.5(b).

8:38-3.7 Complaint and appeal system

- (a) Every HMO shall establish and maintain a system to provide for the presentation and resolution of complaints brought by members or by providers acting on behalf of a member and with the member's consent, regarding any aspect of the HMO's health care services, including, but not limited to, complaints regarding quality of care, choice and accessibility of providers, and network adequacy. All such general complaint systems must, at a minimum, incorporate to the satisfaction of the Commissioner, the following components:
- 1. Written notification to all members and providers of the telephone numbers and business addresses of the HMO employees responsible for complaint resolution;
- 2. A system to record and document the status of all complaints, which shall be maintained for at least three years;
- 3. Availability of an HMO member services representative to assist members, as requested, with complaint procedures;
- 4. Establishment of a specified response time for complaints, not to exceed 30 days from receipt thereof by the HMO;
 - 5. A process describing how complaints are processed and resolved;
- 6. Procedures for follow-up action including the methods to inform the complainant of resolution;
- 7. Procedures for notifying the continuous quality improvement program of all valid complaints related to quality of care; and
- 8. A mechanism for notifying members and providers in writing that they may contact the Department, the Department of Banking and Insurance, in the case of Medicaid enrollees, the Division of Medical Assistance and Health Care Services within the Department of Human Services, or, in the case of Medicare beneficiaries, the Health Care Financing Administration within the United States Department of Health and Human Services, if dissatisfied with the resolution reached through the HMO's internal complaint system.
- (b) Every HMO shall provide for the presentation to the HMO and resolution by the HMO of complaints brought by providers in accordance with N.J.A.C. 8:38- 3.7(a)2, 7.1(a)9 and 7.1(f).
- (c) In addition to the complaint process delineated above, every HMO shall establish and maintain a system for the presentation and resolution of appeals brought by members or by providers acting on behalf of a member and with the member's consent, with respect to the denial, termination or other limitation of covered health care services, hereinafter referred to as utilization management determinations. The appeals process for utilization management determinations shall comply with all of the provisions of N.J.A.C. 8:38-8.4 through 8.7.
- (d) A description of the systems for filing complaints and for appealing utilization management determinations shall be included in the evidence of coverage and member handbook issued to members.
- (e) No member or provider who exercises the right to file a complaint and/or appeal under this section shall be subject to disenrollment or otherwise penalized solely due to such complaint and/or appeal.

8:38-3.8 Submission of documents and data

- (a) The HMO shall submit all membership, utilization, financial, and descriptive plan information to the Departments of Health and Senior Services and Banking and Insurance as requested. This shall include, but is not limited to:
- 1. A quarterly report on forms prescribed by the Department and specified at N.J.A.C. 8:38-11.6(d). This report shall be submitted within 45 days after the end of each quarter; and
- 2. An annual report, a current directory of providers, and a record of all member and provider complaints, inclusive of all malpractice actions, on forms prescribed by the Department, as specified at N.J.A.C. 8:38-11.6. These

reports shall be submitted by March 1 of the following year. The record of member and provider complaints referred to above shall include at least the following:

- i. The total number of complaints and utilization management appeals filed within the last year, categorized by cause and disposition;
- ii. The average length of time for resolution of each complaint and utilization management appeal by cause or category; and
- iii. The number, amount and disposition of malpractice claims settled or adjudicated during the year in which the HMO was a named party to the suit.
- (b) The HMO shall submit a copy of its internal performance indicators to the Department of Health and Senior Services on an annual basis.
- (c) The HMO shall submit continuous quality improvement information as required in N.J.A.C. 8:38-7 to the Department of Health and Senior Services, including, but not limited to:
- 1. A copy of the continuous quality improvement plan and all subsequent revisions to the plan on an annual basis;
- 2. A copy of the reports from the continuous quality improvement plan submitted to the Board of Directors on an annual basis:
- 3. A copy of the performance and outcome data as prescribed by the Department in N.J.A.C. 8:38-7; and
- 4. A copy of the member mailing list as requested by the Department, in accordance with N.J.A.C. 8:38-7.3(f).

8:38-3.9 Provider application for participation and the review panel

- (a) No later than August 29, 2000, an HMO shall establish a committee to review applications submitted by licensed providers to become members of the HMO network.
- 1. The HMO may combine the functions of this committee with another committee, so long as when performing its application review functions, the committee meets the requirements of this section, but the HMO shall not be required to combine the functions of this review committee with the functions of any committee whose function includes credentialing standards.
 - 2. The committee shall be composed of no less than three people.
- 3. At least one of the committee members reviewing a specific application shall be health care providers with knowledge in the applicant provider's scope of professional practice.
- (b) Unless the committee shall notify the applicant within 60 days following receipt of the application that the application is incomplete, specifying in writing the information that is missing, the application shall be deemed complete.
- 1. The committee shall complete its review of a complete application within no more than 90 days of receipt of the complete application.
- 2. The committee shall provide notice of its action on a complete application to the provider in writing.
- 3. If the committee's acceptance of a complete application does not constitute the offer of a contract to the applicant by the HMO, the committee shall set forth in its notice the remaining procedures to be completed prior to the applicant becoming a participating provider, if at all.
- (c) The HMO may establish the factors to be considered by the committee in determining whether an application is complete and whether to accept or reject a complete application.
- 1. The factors considered by the committee shall be in writing, and shall be available for review by applicants upon request.

- 2. The formulas or methods of weighting of factors as specified by the HMO shall be confidential information.
- (d) The HMO may establish its own application forms, but if it does not elect to establish its own form, the HMO shall make available, upon request, a written notice of what information it requires to be submitted to determine an application is complete.
- (e) All applications, notices and guidelines required by this section shall be reviewable upon request by the Department.

SUBCHAPTER 4. MEDICAL DIRECTOR

8:38-4.1 Designation of a medical director

- (a) The HMO shall designate a physician to serve as medical director.
- (b) The medical director or his or her designee shall be designated to serve as the medical director for medical services provided to the HMO's New Jersey members. This physician shall be licensed to practice medicine in New Jersey and may also serve as the overall medical director of the HMO as required in (a) above.

8:38-4.2 Medical director's responsibility

- (a) The medical director shall be responsible for the direction, provision, and quality of medical services provided to members, including, but not limited to:
 - 1. Defining responsibilities and inter-relationships of professional services;
 - 2. Coordinating, supervising and overseeing the functioning of professional services;
 - 3. Evaluating the medical aspects of provider contracts;
 - 4. Overseeing the continuing in-service education of professional staff;
- 5. Providing clinical direction and leadership to the continuous quality improvement and utilization management programs;
- 6. Establishing policies and procedures covering all health care services provided to members;
 - 7. Establishing a committee that has the following responsibilities:
 - i. Establishing mechanisms for ensuring review of provider credentials;
 - ii. Delineating qualifications of participating providers;
- iii. Reviewing credentials of physicians and other providers who do not meet the HMO's established credentialing standards; and
- iv. Establishing a system for verification of provider's credentials, recertification, performance reviews and obtaining information about any disciplinary action against the provider available from the New Jersey Board of Medical Examiners or any other state licensing board applicable to the provider, or the Federal Clearinghouse established pursuant to the Health Care Quality Improvement Act, P.L. 99-660 (42 U.S.C. § 1101 et seq.);
- 8. Implementing a procedure that provides participating providers an opportunity to review and comment on all applicable medical, surgical and dental protocols of the HMO applicable to the area of practice of the provider; and
- 9. Implementing a system through which a member may readily change his or her PCP outside of an annual open enrollment period, and is made aware of this right, which system shall be applicable to all of the HMO's contracts including its POS contracts, regardless of whether referral through the PCP is required in order to access specialty care in-network or to receive benefits out-of-network.
- i. An HMO shall make the selection of a new PCP effective no later than 14 days following the date of the selection when such change is discretionary, and shall make the selection of a new provider immediately effective when change of the PCP is necessitated by termination of the PCP from the network.

SUBCHAPTER 5. HEALTH CARE SERVICES

8:38-5.1 Provision of health care services

- (a) The HMO shall, at a minimum, provide or arrange for the provision to its members all basic comprehensive health care services and all other services enumerated in this subchapter and in N.J.S.A. 26:2J-1 et seq., as it may be amended from time to time.
- 1. If the HMO refers a member out of network, the service or supply shall be covered as an in-network service or supply, such that the HMO is fully responsible for payment to the provider and the member is only responsible for any applicable in-network level copay, coinsurance or deductible for the service or supply.

8:38-5.2 Basic comprehensive health care services

- (a) The HMO shall provide or arrange for the provision of the following basic comprehensive health services as medically necessary:
- 1. Periodic examinations and office visits to a primary care provider for routine and urgent care;
 - 2. Diagnostic and disease detection studies, including laboratory and radiological services;
 - 3. Prenatal care and obstetric care:
- i. In accordance with N.J.S.A. 26:2J-4.9, obstetric care includes 48 hours of inpatient care following a vaginal delivery or a minimum of 96 hours of inpatient care following a caesarean section.
- ii. Notwithstanding the provisions of (a)3i above, a member agreement that provides health care services for post-delivery care to a mother and her newly born child in the home shall not be required to provide for a minimum of 48 hours and 96 hours, respectively, of inpatient care unless such inpatient care is determined to be medically necessary by the attending physician or is requested by the mother.
- 4. Regular pediatric care including newborn care and immunizations as set forth at N.J.A.C. 8:57-8, Childhood Immunization Insurance Coverage;
 - 5. Radiation therapy;
 - 6. Consultations and specialists' services as requested by the primary care provider;
- 7. In accordance with N.J.S.A. 26:2J-4.3a(4), out-of-hospital physical examinations, including related x-rays and diagnostic tests, to include, at a minimum, the following:
- i. For members who are less than two years of age, up to six examinations during the first two years of life; for members who are minors of two years of age or older, one examination at age three, six, nine, 12, 15 and 18 years; and
- ii. For members who are adults less than 40 years of age, one examination every five years; for members who are 40 or more years of age but less than 60 years of age, one examination every three years; and for members who are 60 years of age or older, one examination every two years;
 - 8. Screening examinations prescribed at N.J.S.A. 26:2J-1 et seg., including:
 - i. Pap smears in accordance with N.J.S.A. 26:2J-4.12; and
 - ii. Mammograms in accordance with N.J.S.A. 26:2J-4.4;
 - 9. Physical medicine and rehabilitation services including, but not limited to physical therapy;
- 10. Equipment and supplies for the treatment of diabetes in accordance with N.J.S.A. 26:2J-4.11, and any rules promulgated pursuant thereto, including N.J.A.C. 11:4-49;
- 11. Outpatient evaluative, crisis intervention and short term therapeutic mental health services;
 - 12. Outpatient substance abuse care;
- 13. Medically necessary eye care services for detection and treatment of disease or injury to the eye and children's eye examinations conducted to determine the need for vision correction;
- 14. Inpatient hospital care, including semi-private room accommodations, physicians' and surgeons' services, anesthesia, lab, x-ray and other diagnostic services, drugs and medication, therapeutic services and other services and supplies that are usually provided by the hospital;
 - 15. Outpatient surgical care;
 - 16. Inpatient psychiatric care;

- 17. Inpatient substance abuse care (a minimum of 30 days during any contract year) in a facility licensed to provide residential alcohol and drug abuse services;
- 18. Skilled nursing care (a minimum of 30 days during any contract year) in a licensed long term care facility, as well as services or benefits provided consistent with N.J.S.A. 26:2J-4.21;
 - 19. Home health services (a minimum of 60 home care visits during any contract year); and
 - 20. Hospice services from a Medicare certified hospice agency.

8:38-5.3 Emergency and urgent care services

- (a) The HMO shall establish written policies and procedures governing the provision of emergency and urgent care which shall be distributed to each subscriber at the time of initial enrollment.
 - (b) Emergency and urgent care services shall include, but are not limited to:
 - 1. Medical and psychiatric care, which shall be available 24 hours a day, seven days a week;
- 2. Coverage for trauma services at any designated Level I or II trauma center as medically necessary. Such coverage shall continue at least until, in the judgment of the attending physician, the member is medically stable, no longer requires critical care, and can be safely transferred to another facility. If the HMO requests transfer to a hospital participating in the HMO network, the transfer shall be effected in accordance with Federal regulations at 42 C.F.R. 489.20 and 489.24;
- 3. Coverage for out-of-service area medical care when medically necessary for urgent or emergency conditions where the member cannot reasonably access in- network services;
- 4. Prehospital care and hospital services regardless of location when medically necessary for injury or emergency illness; and
- 5. Upon a member's arrival in a hospital, coverage of a medical screening examination, as required under Federal law and as specified in N.J.A.C. 8:43G-12, as necessary to determine whether an emergency medical condition exists.

8:38-5.4 Supportive services

- (a) The HMO shall provide or arrange for the provision of the following supportive services:
- 1. Ambulance or invalid coach services, as defined at N.J.A.C. 8:40 (therein as "mobility assistance vehicle services"), when authorized by the HMO for non-emergency medical transport;
- 2. Health education services and diabetes self-management education in accordance with N.J.S.A. 26:2J-4.11, and any rules promulgated pursuant thereto, including N.J.A.C. 11:4-49;
 - 3. Nutritional education and counseling;
 - 4. Medical social services; and
- 5. Preventive health services, including voluntary family planning services, and infertility services.

8:38-5.5. Health promotion programs

- (a) In accordance with N.J.S.A. 26:2J-4.6, and rules promulgated pursuant thereto, including N.J.A.C. 11:22-2, HMOs shall provide a health promotion program.
- (b) An HMO shall not be required to provide health wellness promotion program services to members in values exceeding the dollar amounts established by the Commissioner or the Commissioner of Banking and Insurance as published as a public notice periodically in the New Jersey Register.
- (c) The Commissioner, or the Commissioner of Banking and Insurance, in consultation with the Department of the Treasury, shall adjust the threshold amounts in (b) above annually in direct proportion to the increase or decrease in the consumer price index for all urban consumers in the New York City and Philadelphia areas as reported by the United States Department of Labor. The adjustment shall become effective on July 1 of the year in which it is reported, or such other date as may be set forth in the public notice published in the New Jersey Register.

8:38-5.6 Wilm's tumor

In accordance with N.J.S.A. 26:2J-4.1, the HMO shall provide health care services to any member for the treatment of Wilm's tumor, including, but not limited to, autologous bone marrow transplants when

standard chemotherapy treatment is unsuccessful, notwithstanding that any such treatment may be deemed experimental or investigational.

8:38-5.7 Health care services for prescribed drugs

- (a) HMOs which provide pharmacy services, prescription drugs or a prescription drug plan shall comply with the requirements set forth at N.J.S.A. 26:2J- 4.7, as well as the requirements set forth at N.J.A.C. 8:38-18, in the event that the HMO imposes a formulary upon the pharmacy services, prescription drug coverage or prescription drug plan.
- (b) In accordance with N.J.S.A. 26:2J-4.5, an HMO which provides health care services for prescribed drugs approved by the Federal Food and Drug Administration (FDA) shall also provide health care services for prescribed drugs which have not been approved by the FDA if it is recognized to be medically appropriate for the specific treatment for which the drug has been prescribed in one of the following established reference compendia:
 - 1. The American Medical Association drug Evaluations;
 - 2. The American Hospital Formulary Service Drug Information;
 - 3. The United States Pharmacopeia Drug Information; or
 - 4. A clinical study or review article in a major-peer reviewed professional journal.
- (c) Notwithstanding the provisions of this section, coverage shall not be required for any experimental or investigational drug or any drug which the FDA has determined to be contraindicated for the specific treatment for which the drug has been prescribed. Health care services provided pursuant to this section shall be determined and provided to the same extent as other services under the enrollee plan for drugs prescribed for treatments which have been approved by the FDA.
- (d) Any coverage of a drug required by this section shall also include medically necessary services associated with the administration of the drug.

SUBCHAPTER 6. PROVIDER NETWORK

8:38-6.1 Health care service network

- (a) Each HMO shall maintain primary, specialty, ancillary, and institutional services sufficient to meet the requirements in N.J.A.C. 8:38-5.
- (b) Nothing contained in this subchapter shall preclude the New Jersey Department of Human Services, Division of Medical Assistance and Health Services from requiring higher standards for services to Medicaid recipients pursuant to a contract for services between the Division of Medical Assistance and Health Services and the HMO.

8:38-6.2 Primary, specialty and ancillary providers

- (a) The HMO shall maintain an adequate network of primary care providers, specialists, and other ancillary health care personnel to serve the enrolled population at all times. For certificate of authority applications to initiate operations within a service area, this adequacy shall be evaluated based on enrollment projections at the end of 12 months of operation. At a minimum, the network of providers shall include:
 - 1. Medical and other professional staff, as follows:
- i. There shall be a sufficient number of licensed primary care providers (PCPs) under contract with the HMO to provide basic comprehensive health care services;
- ii. There shall be a sufficient number of licensed medical specialists available to HMO members to provide medically necessary specialty care. The HMO shall have a policy assuring access to the specialists identified in (a)1ii(1) through (13) below within 45 miles or one hour driving time, whichever is less, of 90 percent of members within each county or approved sub-county service area:
 - Cardiologist: (1)
 - Dermatologist; (2)
 - (3) Endocrinologist;
 - (4) ENT;
 - (5) General surgeon;(6) Neurologist;

 - (7) Obstetrician/gynecologist;
 - (8) Oncologist;
 - (9) Ophthalmologist;
 - (10) Orthopedist;
 - (11) Oral surgeon:
 - (12) Psychiatrist; and
 - (13) Urologist:
- iii. For specialists not identified in (a)1ii above, the HMO shall have a policy assuring access to such specialists within 45 miles or one hour driving time, whichever is less, of 90 percent of members within each county or approved sub-county service area;
- iv. There shall be a sufficient number of other health professional staff including but not limited to licensed nurses and other professionals available to HMO members to provide basic health care services;
- v. There shall be sufficient licensed optometrists associated with or available to the HMO to assure that, unless referral to an ophthalmologist is determined by the PCP to be medically required and outside the scope of practice of an optometrist, the member can choose to have vision care services provided by a licensed optometrist. The HMO shall have a policy assuring access to these providers, as set forth above in N.J.A.C. 6.2(a) 1ii.
- vi. If the HMO provides pharmacy services, prescription drugs, or a prescription drug plan, no registered pharmacy or pharmacist shall be denied the right to participate as a preferred provider pursuant to the terms of N.J.S.A. 26:2J-4.7.
 - (b) Physicians qualified to function as primary care providers include the following categories:
- 1. Licensed physicians who have successfully completed a residency program accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association in family practice, internal medicine, general practice, obstetrics and gynecology or pediatrics;

- 2. Licensed physicians who do not meet the qualifications in 1 above, but who have been evaluated by the committee required at N.J.A.C. 8:38-4.2(a)7 and found to demonstrate through training, education and experience, equivalent expertise in primary care;
- 3. At the discretion of the HMO, exceptions may be made for appropriate licensed medical specialists to be designated as primary care provider for specified individual members or patient groups who, due to health status or chronic illness, would benefit from medical care management by such a medical specialist.
 - (c) Health care professionals qualified as primary care providers include the following categories:
- 1. Nurse practitioners/clinical nurse specialists certified by the State Board of Nursing in accordance with N.J.S.A. 45:11-45 et seq. in advance practice categories comparable to family practice, internal medicine, general practice, obstetrics and gynecology or pediatrics; and in hospitals or other facilities;
 - 2. Physician assistants licensed by the New Jersey Board of Medical Examiners; and
 - 3. Certified nurse midwives registered by the New Jersey Board of Medical Examiners.
- (d) Geographic access and availability standards for primary care providers (PCPs) shall be as follows:
- 1. There shall be at least two physicians within 10 miles or 30 minutes average driving time or public transit (if available), whichever is less, of 90 percent of the enrolled population.
- 2. The HMO shall demonstrate that the projected PCP network is sufficient to meet adult, pediatric and primary ob/gyn needs of the projected enrollment on the basis of the following assumptions:
- i. Four primary care visits per year per member, averaging one hour per year per member; and
 - ii. Four patient visits per hour, per PCP;
- 3. In order to demonstrate PCP availability, an HMO shall verify that the PCP has committed to provide a specific number of hours for new patients that cumulatively add up to projected clinic hour needs of projected enrollment by county or service area.
- 4. The HMO shall demonstrate that the network of PCPs is sufficient to assure that the following criteria will be met:
- i. Emergencies shall be triaged immediately through the PCP or by a hospital emergency room through medical screening or evaluation;
 - ii. Urgent care shall be provided within 24 hours of notification of the PCP or HMO;
- iii. In both emergent and urgent care, PCPs shall be required to provide seven day, 24 hour access to triage services;
 - iv. Routine appointments shall be scheduled within two weeks; and
 - v. Routine physical exams shall be scheduled within four months.

8:38-6.3 Institutional services

- (a) The HMO shall maintain contracts or other arrangements acceptable to the Department with institutional providers which have the capability to meet the medical needs of members and are geographically accessible. The network of providers shall include:
- 1. At least one licensed acute care hospital including at least licensed medical-surgical, pediatric, obstetrical, and critical care services in any county or service area no greater than 20 miles or 30 minutes driving time, whichever is less, from 90 percent of members within the county or service area;
- 2. Surgical facilities including acute care hospitals, licensed ambulatory surgical facilities, and/or Medicare-certified physicians surgical practices available in each county or service area no greater than 20 miles or 30 minutes driving time, whichever is less, from 90 percent of members within the county or service area:
 - 3. Tertiary and specialized services as follows:
- i. The HMO shall have a contract or otherwise agree to cover medically necessary trauma services at a reasonable cost with all Level I or II trauma centers designated by the New Jersey Department of Health and Senior Services pursuant to N.J.A.C. 8:33P. The member may not be balance billed for any covered trauma services provided by such designated trauma centers.
- ii. The HMO must have a policy assuring access, as evidenced by contract or other agreement acceptable to the Department, to the following specialized services, as determined to be

medically necessary. Such services will be available within 45 miles or 60 minutes average driving time, whichever is less, of 90 percent of members within each county or approved sub-county area:

- (1) At least one hospital providing regional perinatal services;
- (2) A hospital offering tertiary pediatric services;
- (3) In-patient psychiatric services for adults, adolescents and children;
- (4) Residential substance abuse treatment center;
- (5) Diagnostic cardiac catheterization services in a hospital;
- (6) Specialty out-patient centers for HIV/AIDS, sickle cell disease, hemophilia, and cranio facial and congenital anomalies; and
 - (7) Comprehensive rehabilitation services.
- iii. The HMO shall have a policy assuring access, as evidenced by contract or other agreement acceptable to the Department, to the following specialized services, as determined to be medically necessary. Such services will be available within 20 miles or 30 minutes average driving time, whichever is less, of 90 percent of members within each county or approved sub-county area:
 - (1) A licensed long term care facility with Medicare-certified skilled nursing beds;
 - (2) Therapeutic radiation provider;
 - (3) Magnetic resonance imaging center;
 - (4) Diagnostic radiology provider, including x-ray, ultrasound, and CAT scan;
- (5) Emergency mental health service, including a short term care facility for involuntary psychiatric admissions;
 - (6) Out-patient therapy providers for mental health and substance abuse conditions;
 - (7) Licensed renal dialysis provider.

and

- 4. At least one home health agency licensed by the Department to serve each county where 1,000 or more members reside; and
- 5. At least one hospice program certified by Medicare in any county where 1,000 or more members reside.
- (b) The HMO may request, and will be granted, relief from the time and mileage requirements in (a) above where it can document to the satisfaction of the Department that appropriate access to alternative sites is available. Such documentation shall address travel accommodations and travel times, financial hardship placed on families and other logistical details as requested by the Department of a specific HMO.
- (c) In any county or approved sub-county service area in which 20 percent of an HMO's projected or actual membership must rely upon public transportation to access health care services, as documented by U.S. Census Data, the driving times in the criteria in (a) above shall be based upon average transit time using public transportation. The HMO shall demonstrate how it will meet this requirement in its application.

SUBCHAPTER 7. CONTINUOUS QUALITY IMPROVEMENT

8:38-7.1 Continuous quality improvement program

- (a) The HMO shall have a system-wide continuous quality improvement program to monitor the quality and appropriateness of care and services provided to members. This program shall be under the direction of the medical director or his or her designee, who shall be a physician, and shall be based on a written plan which is reviewed at least annually and revised as necessary. The plan shall describe at least:
 - 1. The scope and purpose of the program;
 - 2. The organizational structure of quality improvement activities;
- 3. Duties and responsibilities of the medical director and/or designated physician responsible for continuous quality improvement activities;
- 4. Contractual arrangements, where appropriate, for delegation of quality improvement activities:
 - 5. Confidentiality policies and procedures;
- 6. Specification of standards of care, criteria and procedures for the assessment of the quality of services provided and the adequacy and appropriateness of health care resources utilized;
- 7. A system of ongoing evaluation activities, including individual case reviews as well as pattern analysis;
- 8. A system of focused evaluation activities, particularly for frequently performed and/or highly specialized procedures;
- 9. A system of monitoring member satisfaction and network providers' response and feedback on HMO operations;
- 10. The procedures for conducting peer review activities which shall include providers within the same discipline and area of clinical practice; and
- 11. A system for evaluation of the effectiveness of the continuous quality improvement program.
- (b) The board of directors of the HMO shall be kept apprised of continuous quality improvement activities and shall be provided at least annually with regular written reports from the program delineating quality improvements, performance measures used and their results, and demonstrated improvements in clinical and service quality.
- (c) There shall be a multidisciplinary continuous quality improvement committee responsible for the implementation and operations of the program. The structure of the committee shall include representation from the medical, nursing and administrative staff, with substantial involvement of the medical director of the HMO.
- (d) The program shall monitor the availability, accessibility, continuity and quality of care on an ongoing basis. Indicators of quality care for evaluating the health care services provided by all participating providers shall be identified and established and shall include at least:
- 1. A mechanism for monitoring patient appointments and triage procedures, discharge planning services, linkage between all modes and levels of care and appropriateness of specific diagnostic and therapeutic procedures, as selected by the continuous quality improvement program;
- 2. A mechanism for evaluating all providers of care. The findings from a health care facility's internal quality assurance program may be used to supplement, but shall not fully constitute, the HMO's assessment of patient care; and
- 3. A system to monitor provider and member access to utilization management services including at least waiting times to respond to phone requests for service authorization, member urgent care inquiries, and other services required in N.J.A.C. 8:38-8.3.
- (e) The HMO shall follow up on findings from the program to assure that effective corrective actions have been taken, including at least policy revisions, procedural changes and implementation of educational activities for members and providers.
- (f) Continuous quality improvement activities shall be coordinated with other performance monitoring activities including utilization management, risk management, and monitoring of member and provider complaints.

- (g) The HMO shall maintain documentation of the quality improvement program in a confidential manner. This documentation shall be available to the Commissioner or his or her designee and shall include:
 - 1. Minutes of quality improvement committee meetings; and
- 2. Records of evaluation activities, performance measures, quality indicators and corrective plans and their results or outcomes.

8:38-7.2 External quality audit

- (a) Each HMO shall submit, as part of the comprehensive assessment review process, evidence of the most recent external quality audit that has been conducted within three years of the date of the comprehensive assessment review. Such audit shall be performed by an external quality review organization (EQRO) approved by the Department.
- (b) The report shall describe in detail the HMO's conformance to performance standards established by the (EQRO), other national standard-setting bodies for HMOs, and/or the rules within this chapter. The report shall also describe in detail any corrective actions proposed and/or undertaken and approved by the (EQRO). The report shall be submitted to the Department within 60 days of its receipt in final form by the HMO.
- (c) The HMO shall not be required to receive "accreditation" or "certification" or other such status granted by the (EQRO). If the HMO attains "accreditation" or "certification" or other such status granted by the (EQRO) within the 12 months prior to the Department's comprehensive assessment review, the HMO shall be exempted from examination by the Department in any area in which the Commissioner determines that the EQRO's) review demonstrated specific compliance with standards substantially equivalent to those contained in this chapter.
- (d) The Commissioner may grant an HMO a deferral of the above requirement for an external quality audit for a 12-month period if it is in the initial three years of start-up operations, and it demonstrates a financial or operational hardship.

8:38-7.3 Performance and outcome measures

- (a) The Department shall develop a performance and outcome measurement system for monitoring the quality of care provided to HMO members. The data collected through this system may be used by the Department to:
 - 1. Assist HMOs and their providers in quality improvement efforts;
- 2. Provide the Department with information on the performance of HMOs for regulatory oversight:
 - 3. Support efforts to inform consumers about HMO performance;
 - 4. Promote the standardization of data reporting by HMOs and providers; and
 - 5. Any other purpose consistent with this chapter and N.J.S.A. 26:2J-1 et seq.
- (b) The performance and outcome measures shall include population-based and patient-centered indicators of quality of care, appropriateness, access, utilization, and satisfaction. To minimize costs to HMOs, providers, and the Department, performance measures shall incorporate, when possible, data routinely collected or available to the Department from other sources. Data for these performance measures may include, but not be limited to, the following:
 - 1. Indicator data collected by HMOs from chart reviews and administrative data bases;
 - 2. Member and patient satisfaction surveys;
 - 3. Provider surveys;
- 4. Quarterly and annual reports submitted by HMOs to the Department as specified in N.J.A.C. 8:38-3.7;
 - 5. Computerized health care encounter data: and
- 6. Data collected by the Department for administrative, epidemiological and other purposes, such as the State cancer registry, vital records, and hospital UB-92 records.
- (c) HMOs shall submit such performance and outcome data as the Department may request from time to time.

- (d) The Department shall make, when appropriate, statistically valid adjustments to account for demographic variations among HMOs. Each HMO shall have opportunity to comment on the compilation and interpretation of the data before its release to consumers.
- (e) The Department shall conduct audits of each HMO's performance and outcome data including desk and on-site audits.
- (f) The Department shall conduct or arrange for periodic member satisfaction surveys. The HMO shall provide the Department with the member mailing list, upon request, to be used to select samples of the HMO's membership for the surveys.
 - (g) The Department shall ensure the confidentiality of patient specific information.
- (h) The Department shall take all necessary measures to reduce duplicative reporting of information to State agencies.

8:38-7.4 Healthcare Data Committee

- (a) The Department shall establish a Healthcare Data Committee (HeDaC) to assist the Department in developing a performance measurement and assessment system for monitoring the quality of care provided to HMO members as described in N.J.A.C. 8:38-7.3.
- 1. The HeDaC shall be comprised and shall perform the functions as set forth at N.J.A.C. 8:38A-4.13(e).

SUBCHAPTER 8. UTILIZATION MANAGEMENT

8:38-8.1 Utilization management program

- (a) The HMO shall establish and implement a comprehensive utilization management program to monitor access to and appropriate utilization of health care and services. The program shall be under the direction of the medical director or his or her designee, who shall be a physician, and shall be based on a written plan that is reviewed at least annually by the HMO, and is available for review by the Department upon request. The plan shall identify at least:
 - 1. Scope of utilization management activities;
- 2. Procedures to evaluate clinical necessity, access, appropriateness, and efficiency of services;
 - 3. Mechanisms to detect underutilization and overutilization;
 - 4. Clinical review criteria and protocols used in decision-making;
 - 5. Mechanisms to ensure consistent application of review criteria and uniform decisions;
- 6. Development of outcome and process measures for evaluating the utilization management program;
- 7. System for providers and members to appeal utilization management determinations in accordance with the procedures set forth at N.J.A.C. 8:38-8.4 through 8.7; and
- 8. A mechanism to evaluate member satisfaction with the complaint and appeals systems set forth at N.J.A.C. 8:38-3.6 and at 8:38-8.4 through 8.7. Such evaluation shall be coordinated with the performance monitoring activities conducted pursuant to the continuous quality improvement program set forth in N.J.A.C. 8:38-7.
- (b) Utilization management determinations shall be based on written clinical criteria and protocols developed with involvement from practicing physicians and other licensed health care providers within the network and based upon generally accepted medical standards. These criteria and protocols shall be periodically reviewed and updated, and shall, with the exception of internal or proprietary quantitative thresholds for utilization management, be readily available, upon request, to members and participating providers in the relevant practice areas.

8:38-8.2 Utilization management staff availability

- (a) A registered professional nurse or physician shall be immediately available by phone seven days a week, 24 hours a day, to render utilization management determinations for providers.
- (b) For routine utilization-related inquiries, the HMO shall provide all members and providers with a toll free telephone number by which to contact utilization management staff on at least a five-day, 40 hours a week basis.
- (c) All members must have immediate phone access seven days a week, 24 hours a day, to their primary care provider or his or her authorized on-call back-up provider. When these providers are unavailable, a registered nurse or physician on the utilization management staff must be available to respond to inquiries concerning emergency or urgent care.

8:38-8.3 Utilization management determinations

- (a) The HMO shall have written policies and procedures that address responsibilities and qualifications of staff who render determinations to authorize admissions, services, procedures or extensions of stay.
- (b) All determinations to deny or limit an admission, service, procedure or extension of stay shall be rendered by a physician. The determination shall be directly communicated by the physician to the provider or, if this is not possible, the provider shall be supplied with the physician's name, telephone number, and where he or she can be reached. The physician shall be available immediately in urgent or emergency cases and on a timely basis for all other cases as required by the medical exigencies of the situation. The physician

shall be under the clinical direction of the medical director responsible for medical services provided to the HMO's New Jersey members. Such determinations shall be made in accordance with clinical and medical necessity criteria developed pursuant to N.J.A.C. 8:38-8.1(b) and the evidence of coverage.

- (c) All determinations shall be made on a timely basis, as required by the exigencies of the situation.
- (d) An HMO shall not retroactively deny reimbursement for a covered service provided to a member by a provider who relied upon the written or oral authorization of the HMO or its agents prior to providing the service to the member, except in cases where there was material misrepresentation or fraud.
- (e) A member or provider acting on behalf of a member shall receive upon request a written notice of any determination to deny coverage or authorization for services required in this subchapter or in the evidence of coverage, which shall be subject to appeal in accordance with N.J.A.C. 8:38-8.5, 8.6 and 8.7. The written notice of determination shall include an explanation of the appeal process.

8:38-8.4 Appeals of utilization management determinations

- (a) All HMO members, and any provider acting on behalf of a member with the member's consent, may appeal any utilization management determination resulting in a denial, termination, or other limitation of covered health care services in accordance with the provisions of N.J.A.C. 8:38-8.5 through 8.7. All members and providers shall be provided with a written explanation of the appeal process in the member handbook and upon the conclusion of each stage in the process as described in N.J.A.C. 8:38-8.5 through 8.7. The appeal process shall consist of an informal internal review by the HMO (stage 1 appeal), a formal internal review by the HMO (stage 2 appeal), and a formal external review (stage 3 appeal) by an independent utilization review organization (IURO) through the Independent Health Care Appeals Program established pursuant to N.J.S.A. 26:2S-11, as further described at N.J.A.C. 8:38A-5.
- (b) Nothing in the HMO's policies, procedures or provider agreement shall prohibit a member or provider (on behalf of a member) from discussing or exercising the right to an appeal available under N.J.A.C. 8:38-8.5 through 8.7.

8:38-8.5 Informal internal utilization management appeal process (Stage 1)

Each HMO shall establish and maintain an informal internal appeal process (stage 1 appeal) whereby any member, or any provider acting on behalf of a member, with the member's consent, who is dissatisfied with any HMO utilization management determination, shall have the opportunity to speak to and appeal that determination with the HMO medical director and/or physician designee who rendered the determination. All such stage 1 appeals shall be concluded as soon as possible in accordance with the medical exigencies of the case, which in no event shall exceed 72 hours in the case of appeals from determinations regarding urgent or emergency care (including all situations in which the member is confined as an inpatient), and five business days in the case of all

other appeals. If the appeal is not resolved to the satisfaction of the member at this level, the HMO shall provide the member and/or the provider with a written explanation of his or her right to proceed to a stage 2 appeal, including the applicable time limits, if any, for making the appeal, and to whom the appeal should be addressed.

8:38-8.6 Formal internal utilization management appeal process (Stage 2)

- (a) Each HMO shall establish and maintain a formal internal appeal process (stage 2 appeal) whereby any member or any provider acting on behalf of a member with the member's consent, who is dissatisfied with the results of the stage 1 appeal, shall have the opportunity to pursue his or her appeal before a panel of physicians and/or other health care professionals selected by the HMO who have not been involved in the utilization management determination at issue.
- (b) The formal internal utilization management appeal panel shall have available consultant practitioners who are trained or who practice in the same specialty as would typically manage the case at issue or such other licensed health care professional as may be mutually agreed upon by the parties. In no event, however, shall the consulting practitioner or professional have been involved in the utilization management determination at issue. The consulting practitioner or professional shall participate in the panel's review of the case, if requested by the member and/or provider.
- (c) All such stage 2 appeals shall be acknowledged by the HMO, in writing, to the member or provider filing the appeal within 10 business days of receipt.

- (d) All such stage 2 appeals shall be concluded as soon as possible after receipt by the HMO in accordance with the medical exigencies of the case, which in no event shall exceed 72 hours in the case of appeals from determinations regarding urgent or emergent care (including all situations in which the member is confined as an inpatient) and, except as set forth in (e) below, 20 business days in the case of all other appeals.
- (e) The HMO may extend the review for up to an additional 20 business days where it can demonstrate reasonable cause for the delay beyond its control and where it provides a written progress report and explanation for the delay to the satisfaction of the Department, with notice to the member and/or provider within the original 20 business day review period.
- (f) If the stage 2 appeal is denied, the HMO shall provide the member and/or provider with written notification of the denial and the reasons therefor together with a written notification of his or her right to proceed to an external (stage 3) appeal. This notification shall include specific instructions as to how the member and/or provider may arrange for an external appeal and shall also include any forms required to initiate such an appeal.
- (g) In the event that the HMO fails to comply with any of the deadlines for completion of the internal utilization management determination appeals set forth in N.J.A.C. 8:38-8.5 or 8.6, or in the event that the HMO for any reason expressly waives its rights to an internal review of any appeal, then the member and/or provider shall be relieved of his or her obligation to complete the HMO internal review process and may, at his or her option, proceed directly to the external appeals process set forth at N.J.A.C. 8:38-8.7.

8:38-8.7 External appeals process

- (a) Any HMO member, and any provider acting on behalf of a member, with the member's consent, who is dissatisfied with the results of the internal appeal process set forth at N.J.A.C. 8:38-8.5 through 8.6 above, shall have the right to pursue his or her appeal to an independent utilization review organization (IURO) in accordance with the procedures set forth below (stage 3 appeal). Except as set forth in N.J.A.C. 8:38-8.6(g), the right to an external appeal under this section shall be contingent upon the member's full compliance with both stages of the HMO internal appeal process set forth at N.J.A.C. 8:38-8.5 and 8.6.
- (b) To initiate an external appeal, a member and/or provider shall, within 60 days from receipt of the written determination of the stage 2 internal appeal panel under N.J.A.C. 8:38-8.6(f), file a written request with the Department. The request shall be filed on the forms automatically provided to the member in accordance with N.J.A.C. 8:38-8.6(f), and shall include both the fee specified in (c) below and a general release executed by the member for all medical records pertinent to the appeal. The request shall be mailed to the following address:

Department of Health and Senior Services
Office of Managed Care
Division of Health Care Systems Analysis
PO Box 360
Trenton, New Jersey 08625-0360

- (c) The fee for filing an appeal shall be \$25.00, payable by check or money order to the "New Jersey Department of Health and Senior Services." Upon a determination of financial hardship, the fee may be reduced to \$2.00. Financial hardship may be demonstrated by the member through evidence that one or more members of the household is receiving assistance or benefits under the Pharmaceutical Assistance to the Aged and Disabled, Medicaid, NJ KidCare, General Assistance, SSI, or New Jersey Unemployment Assistance.
- (d) Upon receipt of the appeal, together with the executed release and the appropriate fee, the Department shall immediately assign the appeal to an IURO in accordance with N.J.A.C. 8:38-8.8, for review.
- (e) Upon receipt of the request for appeal from the Department, the IURO will conduct a preliminary review of the appeal and accept it for processing if it determines that:
 - 1. The individual was or is a member of the HMO;

- 2. The service which is the subject of the complaint or appeal reasonably appears to be a covered service under the benefits provided by contract to the member;
- 3. Except as set forth at N.J.A.C. 8:38-8.6(g), the member has fully complied with both the stage 1 and stage 2 appeals available pursuant to N.J.A.C. 8:38-8.5 and 8.6; and
- 4. The member has provided all information required by the IURO and Department to make the preliminary determination including the appeal form and a copy of any information provided by the HMO regarding its decision to deny, reduce or terminate the covered service, and a fully executed release to obtain any necessary medical records from the HMO and any other relevant health care provider.
- (f) Upon completion of the preliminary review, the IURO shall immediately notify the member and/or provider in writing as to whether the appeal has been accepted for processing and if not so accepted, the reasons therefor.
- (g) Upon acceptance of the appeal for processing, the IURO shall conduct a full review to determine whether, as a result of the HMO's utilization management determination, the member was deprived of medically necessary covered services. In reaching this determination the IURO shall take into consideration all pertinent medical records, consulting physician reports and other documents submitted by the parties, any applicable, generally accepted practice guidelines developed by the Federal government, national or professional medical societies, boards and associations, and any applicable clinical protocols and/or practice guidelines developed by the HMO pursuant to N.J.A.C. 8:38-8.1(b).
- (h) The full review referenced in (g) above shall initially be conducted by a registered professional nurse or a physician licensed to practice in New Jersey. When necessary, the IURO shall refer all cases for review to a consultant physician in the same specialty or area of practice who would generally manage the type of treatment that is the subject of the appeal. All final recommendations of the IURO shall be approved by the medical director of the IURO.
- (i) The IURO shall complete its review and issue its recommended decision as soon as possible in accordance with the medical exigencies of the case which, except as provided for in this subsection, in no event shall exceed 30 business days from receipt of all documentation necessary to complete the review. The IURO may, however, extend its review for a reasonable period of time as may be necessary due to circumstances beyond its control, except that in no event shall it render its determination later than 90 days following receipt of a completed application. In the event the IURO needs to extend its review period, it shall, prior to the conclusion of the 30 business day review, provide written notice to the member and/or provider, to the Department, and to the HMO setting forth the status of its review and the specific reasons for the delay.
- 1. Notwithstanding (i) above, if the appeal involves care for an urgent or emergency case, the IURO shall complete its review within no more than 48 hours following its receipt of the appeal.
- (j) If the IURO determines that the member was deprived of medically necessary covered services, the IURO shall recommend to the member and/or provider who filed the appeal, the HMO and the Department, the appropriate covered health care services the member should receive.
- (k) Within 10 business days of the receipt of the determination of the IURO as set forth in (j) above, the HMO shall submit a written report to the IURO, member and provider if the provider made the appeal on behalf of the member with the member's consent, and the Department indicating whether the HMO will accept and implement or reject the recommendations of the IURO in whole or in part.
- 1. The written report of the HMO shall state with specificity the reasons for rejection, in whole or in part, of the recommendation(s) of the IURO, and the HMO's report shall not be complete unless such reasons are set forth in the report.
- (I) Nothing in this section shall limit the authority of the Division of Medical Assistance and Health Services (DMAHS) or the Department of Human Services (DHS) to adopt in any contract to provide HMO services to Medicaid recipients, its own process for appeals of utilization management determinations. At the request of the Commissioner of Human Services, the Commissioner shall adopt, in accordance with N.J.S.A. 52:14B-1 et seq. and N.J.A.C. 1:30, any such appeals process proposed by DMAHS or DHS as the exclusive appeals process for all Medicaid HMO members, if he or she find that it meets or exceeds the standards set forth in this chapter.

8:38-8.8 General requirements for independent utilization review organizations

- (a) The Department shall, from time to time, enter into contracts with as many independent utilization review organizations as it deems necessary to conduct the external appeals provided for under N.J.A.C. 8:38-8.7. The physician reviewers of the IUROs selected by the Department shall be experienced in managed care utilization review. The contracts shall set forth all terms which the Department deems necessary to ensure a member's right of appeal under N.J.A.C. 8:38-8.7 including, but not limited to, an assessment of separate costs to the HMO for the initial IURO review under N.J.A.C. 8:38-8.7(e) and the full review under N.J.A.C. 8:38-8.7(g).
- (b) As a part of the contract process set forth in (a) above, all IUROs shall submit to the Department and shall maintain current, a list identifying all HMOs, health insurers, health care facilities and other health care providers with whom the IURO maintains any health related business arrangements. This list shall include a brief description of the nature of any such arrangement.
- (c) Upon receipt of any request for an external appeal under N.J.A.C. 8:38- 8.7(d) above, the Department shall assign that appeal to one of the approved IUROs on a random basis. The Commissioner reserves the right to deny any assignment to any IURO if, in his or her determination, such an assignment would result in a conflict of interest or would otherwise create an appearance of impropriety. In reaching such a determination, the Commissioner shall take into consideration the list required of IUROs in (a) above.

8:38-8.9 Department review of HMO actions on IURO recommendations

- (a) The Department shall review records of HMO reports submitted pursuant to N.J.A.C. 8:38-8.7(k) at least annually to determine whether a carrier exhibits a pattern of noncompliance with the recommendations of an IURO as well as possible violations of patient rights or other applicable laws.
- (b) If the Department determines that an HMO exhibits a pattern of noncompliance with the recommendations of an IURO, the Department shall review:
 - 1. Whether the HMO's noncompliance is with a specific set of recommendations;
- 2. Whether the HMO's noncompliance is with a specific IURO (in the event more than one IURO participates in the external appeal program); and
 - 3. The HMO's utilization management program.
- (c) If the Department determines that the HMO's utilization management program is not in compliance with either the HMO's utilization management standards set forth in accordance with N.J.A.C. 8:38-8.1, or other relevant laws, the Department shall take action(s) as deemed appropriate, in the discretion of the Commissioner, if any, pursuant to N.J.A.C. 8:38-2.14.
- (d) If the Department determines that the HMO is in violation of member rights or other applicable requirements, the Department shall take action(s) as deemed appropriate, in the discretion of the Commissioner, if any, pursuant to N.J.A.C. 8:38-2.14.
- (e) A pattern of noncompliance shall include, but not be limited to, multiple incidents of refusal to follow the recommendations of the IURO, in whole or in part, within a 12 month period, when such recommendations require the HMO to provide covered services or benefits therefor to a member.

SUBCHAPTER 9. MEMBER RIGHTS AND RESPONSIBILITIES; DISCLOSURES TO CONSUMERS

8:38-9.1 Policies and procedures

- (a) The HMO shall establish and implement written policies and procedures regarding the rights of members and the implementation of these rights.
- (b) The HMO shall provide each member with a current copy of a member's benefit handbook, including at least:
 - 1. A complete statement of the member's rights;
- 2. A description of all complaint and grievance procedures, including the address and telephone numbers of the complaint offices of the HMO and of the Departments of Health and Senior Services and Banking and Insurance; and
- 3. A clear and complete summary of the evidence of coverage, including limitations, exclusions, and procedures for accessing out of network services, as required by N.J.S.A. 26:2J-8(b), and the responsibility of the subscriber to pay copayments, deductibles and coinsurance, as appropriate, in terms relevant to the type of product(s) purchased.
- i. HMOs shall clearly distinguish any differences in the member's financial responsibility for accessing services within and outside of the HMO's network.
- ii. HMOs shall explain the member's responsibility to pay for charges incurred that are not covered under or authorized pursuant to the policy or contract.
- iii. With respect to point of service contracts, HMOs shall explain the member's responsibility to pay for charges that exceed what the HMO determines are customary and reasonable (usual and customary, or usual, customary and reasonable, as appropriate) for services that are covered under the out-of-network component of the contract.
- (c) HMOs shall, upon request, provide a written document to consumers setting forth the information required to be disclosed to members.
- 1. The HMO shall not be required to provide the consumer with the same level of detail that is provided to members in the provider directory pursuant to (d)6 below, but the HMO shall provide at least the following information:
- i. The number of medical providers categorized by specialty by county in the carrier's network;
 - ii. The number of hospitals categorized by county in the HMO's network;
- iii. The approximate percentage of the medical providers in the HMO's network that are board certified, and the date on which the calculation of the percentage was last performed;
- iv. The waiting time criteria that the HMO utilizes in its selection of providers for participation in the HMO's network, if any, including a statement that no such criteria apply in those instances in which the HMO does not consider patient waiting times for appointments for routine and urgent care in selecting participating providers;
- v. A statement that consumers can check with providers directly to find out if the provider is a participating provider; and
- vi. A statement that the consumer may obtain more detailed information, including a current provider directory (if not already included), and the process by which consumers may obtain the information free of charge.
- (1) HMOs that elect to make their lists of participating providers available through an electronic database accessible to the public shall not substitute electronic access to the information as the only means by which consumers may obtain the information free of charge.
- 2. The information provided to consumers may be in a single document or multiple documents, except that when an HMO uses multiple documents for its provider lists, the HMO shall cross reference in each provider lists all other lists of health care providers for which the HMO is required to provide coverage, or benefits therefor, pursuant to statute or rule.
 - (d) The statement of the member's rights shall include at least the right:
- 1. To available and accessible services when medically necessary, including availability of care 24 hours a day, seven days a week for urgent or emergency conditions. The statement shall include a reminder that the "911" emergency response system should be called whenever a member has a potentially life- threatening condition. This information shall also be provided on the membership identification cards;

- 2. To be treated with courtesy and consideration, and with respect for the member's dignity and need for privacy:
- 3. To be provided with information concerning the HMO's policies and procedures regarding products, services, providers, appeals procedures and other information about the organization and the care provided;
- 4. To choose a primary care provider within the limits of the covered benefits and availability and included as participating providers in the plan network;
- 5. To be afforded a choice of specialists among participating network providers following an authorized referral, subject to their availability to accept new patients;
- 6. To obtain a current directory of participating providers in the HMO network upon request, including addresses and telephone numbers, and a listing of providers who accept members who speak languages other than English;
- 7. To obtain assistance and referral to providers with experience in treatment of patients with chronic disabilities:
- 8. To receive from the member's physician(s) or provider, in terms that the member understands, an explanation of his or her complete medical condition, recommended treatment, risk(s) of the treatment, expected results and reasonable medical alternatives, whether or not these are covered benefits. If the member is not capable of understanding the information, the explanation shall be provided to his or her next of kin or guardian and documented in the member's medical record;
- 9. To be free from balance billing by providers for medically necessary services that were authorized or covered by the HMO except as permitted for copayments, coinsurance and deductibles by contract;
 - 10. To formulate and have advance directives implemented;
- 11. To all the rights afforded by law or regulation as a patient in a licensed health care facility, including the right to refuse medication and treatment after possible consequences of this decision have been explained in language the member understands;
- 12. To prompt notification, as required in this chapter, of termination or changes in benefits, services or provider network; and
- 13. To file a complaint or appeal with the HMO or the Departments of Health and Senior Services and Banking and Insurance and to receive an answer to those complaints within a reasonable period of time.
- (e) The HMO shall establish and implement written policies and procedures regarding the responsibilities of members, such as financial responsibilities, including copayments and deductibles. A complete statement of these responsibilities shall be included in the member's benefit handbook.

SUBCHAPTER 10. MEDICAL RECORDS

8:38-10.1 Policies and procedures

- (a) The HMO shall develop and implement a policy for the transfer of medical records of members whenever the following occur:
 - 1. Change of physician or other provider;
 - 2. Disenrollment of member from HMO; or
 - 3. Other circumstances where requested by members or former members;
- (b) Transfer of members' medical records as maintained by the HMO shall be completed within 30 days of the occurrence of events specified at (a)1, 2, or 3 above.

8:38-10.2 Confidentiality of medical records

Any data or information pertaining to the diagnosis, treatment, or health of any member or applicant obtained from the member or from any provider by any HMO shall be held in confidence. The data or information shall not be disclosed to any person, except to the extent that it may be necessary to carry out the purposes of this chapter, or upon the express consent of the member or applicant; or pursuant to state or court order for the production of evidence or the discovery thereof; or in the event of claim or litigation between such member and the HMO wherein such data or information is pertinent as otherwise provided by law. An HMO shall be entitled to claim any statutory privileges against such disclosure which the provider who furnished such information to

the health organization is entitled to claim. An HMO may also release aggregate data related to the diagnosis, treatment, or health of all or groups of members or applicants where the identity of every member is kept confidential and cannot be determined by the manner in which the data is released and presented.

8:38-10.3 Maintenance of medical records

Any medical records directly maintained by the HMO shall be organized in a uniform format across all records subject to the requirements of applicable law. The HMO shall have policies governing the contents of medical records.

8:38-10.4 Copies of medical records

Members or their legally authorized representatives shall have a right to inspect and obtain a copy of their medical records maintained by the HMO. Charges for copies of medical records shall be based upon actual costs, not to exceed prevailing community rates for photocopying.

8:38-10.5 Medical record retention

Medical records maintained by HMO's shall be protected against loss, destruction, or unauthorized use and retained for at least 10 years or until the member reaches age 23 years, whichever is longer.

SUBCHAPTER 11. FINANCIAL STANDARDS AND REPORTING

8:38-11.1 Minimum net worth

- (a) In order to obtain a certificate of authority, an HMO shall have a minimum net worth, determined on a SAP basis, of at least \$1,500,000 in cash or cash equivalents, as adjusted annually by the CPI, together with such other guarantees and assets as the Commissioner and Commissioner of Banking and Insurance may determine appropriate to assure the solvency of the HMO, based on its business plan, beginning on July 1, 1997.
- (b) Except as (d) below applies, in order to maintain its certificate of authority, an HMO shall maintain at all times a minimum net worth, determined on a SAP basis, equal to the greater of:
 - 1. \$1,000,000 adjusted annually by the CPI, beginning on July 1, 1997;
- 2. Two percent of the annual premium revenues as reported by the HMO on its most recent annual financial statement filed with the Commissioner and Commissioner of Banking and Insurance for the first \$150,000,000 of premium reported and one percent of the annual premium in excess of the first \$150,000,000 of premium reported;
- 3. An amount equal to the sum of three months of uncovered health care expenditures, as reported on the financial statement filed most recently with the Commissioner and Commissioner of Banking and Insurance; or
- 4. An amount equal to the sum of eight percent of the annual health care expenditures (not including those expenditures paid on a capitated basis to a provider and those made on a managed hospital payment basis), as reported on the four quarterly financial statements most recently filed with the Commissioner and Commissioner of Banking and Insurance, plus four percent of the annual hospital expenditures paid on a managed hospital payment basis, as reported in the four quarterly financial statements most recently filed with the Commissioner and Commissioner of Banking and Insurance. If an HMO is issued an initial certificate of authority on or after July 1, 1997, its minimum net worth shall be phased in over a 48 month period, running from the date that its new certificate of authority is effective, as follows:
- i. Twenty-five percent of the amount required in (b)4 above, or the greater of (b)1, 2 or 3 above, whichever is greatest, until the end of the 23rd month following the month in which its new certificate of authority was effective;
- ii. Fifty percent of the amount required in (b)4 above, or the greater of (b)1, 2 or 3 above, whichever is greatest from months 24 through 35;
- iii. Seventy-five percent of the amount required in (b)4 above, or the greater of (b)1, 2 or 3 above, whichever is greatest, from months 36 through 47; and
- iv. One hundred percent of the amount required in (b)4 above beginning in the 48th month following the month in which its new certificate of authority was effective.
- (c) In order to maintain its certificate of authority, a minimum of 60 percent of an HMO's admitted assets shall be cash, cash equivalents, investments as set forth at N.J.S.A. 17B:20-1a, or other forms of investments acceptable to the Commissioner considering the amount of the HMO's assets and the proportion of admitted assets to the HMO's minimum net worth requirement.
- (d) Every HMO shall submit a capital and surplus (minimum net worth) guarantee on a form established and available from the Department of Banking and Insurance, executed by an affiliate or parent of the HMO that is not in an unsafe or unsound financial condition, consistent with N.J.A.C. 11:2-27, Determination of Insurers in a Hazardous Financial Condition, incorporated herein by reference, except that an HMO that has no such parent or affiliate available to execute a capital and surplus guarantee shall demonstrate to the satisfaction of the Commissioner of Banking and Insurance that other additional financial resources are available to the HMO to maintain the HMO's minimum net worth requirement. All guarantors shall satisfy the following requirements:
- 1. The guarantor shall have liquid assets, letters of credit or a similar instrument available to support the guarantee in a manner and amount acceptable to the Commissioner of Banking and Insurance.
- 2. If the guarantor is publicly held, the HMO shall submit the guarantor's quarterly and annual Securities and Exchange Commission (SEC) filing no later than 15 days after such filing has been made with the SEC. If not publicly held, the HMO shall submit the guarantor's unaudited quarterly financial statement no later than 45 days after the end of the calendar quarter.

- 3. All guarantors shall meet the following requirements:
- i. The guarantor shall be a United States corporation actively engaged in business for a period of not less than five years;
- ii. The guarantor shall have a satisfactory evaluation from Dun and Bradstreet, Standard and Poor's, Duff and Phelps or Moody's for at least three years;
 - iii. The guarantor shall have a net worth of at least \$25 million; and
- iv. If the guarantor fails to meet any of the requirements in (d)3i through iii above, a letter of credit or other form of financial security acceptable to the Commissioner of Banking and Insurance shall be required.
- (e) In determining net worth, a debt shall not be considered fully subordinated unless the subordination clause states that:
- 1. Principal and/or interest shall be paid to the lender only from free and divisible surplus as verified by the audited financial statement of the HMO;
- 2. Upon the dissolution or liquidation of the HMO, no payment shall be made with respect to the surplus note or other note made with that lender unless and until all other liabilities of the HMO have been paid in full; and
- 3. Written approval shall be obtained from the Commissioner of Banking and Insurance prior to any full or partial repayment of any principal or interest under the note.
- (f) Any debt incurred by a note meeting the requirements of (e) above and which is otherwise acceptable to the Commissioner of Banking and Insurance shall not be considered a liability, but shall be reported as equity by the HMO.
- (g) The interest expenses relating to the repayment of any fully subordinated debt shall be a covered expenditure.
- (h) Every HMO shall be subject to the standards and corrective actions set forth at N.J.A.C. 11:2-27, Determination of Insurers in a Hazardous Financial Condition, which shall be in addition to the requirements of N.J.A.C. 8:38-11.6(f).
- (i) No HMO shall enter into transactions for loans or other transfers of funds from or to the HMO without providing at least 30 days prior written notice of the transaction to the Commissioner and the Commissioner of Banking and Insurance.
- 1. The Commissioner of Banking and Insurance may disapprove the transaction if, in the Commissioner's opinion, the transaction will adversely affect the HMO and cause it to be in a hazardous financial condition, in accordance with N.J.A.C. 11:2-27.
- 2. The Commissioner or the Commissioner of Banking and Insurance may disapprove the transaction pending receipt of additional information from the HMO.
 - 3. The disapproval shall specify in writing the reasons for the disapproval.
- i. If the disapproval includes a request for additional information, the disapproval shall include the date by which the additional information is due from the HMO.
- ii. An HMO shall have no less than five business days in which to respond to a disapproval with a request for more information.
- 4. If the Commissioner or Commissioner of Banking and Insurance does not disapprove of the transaction within 30 days of the date that the written notice is received by the Department of Banking and Insurance, the transaction shall be deemed approved.
- i. With respect to filings for which additional information has been requested, if the Commissioner or the Commissioner of Banking and Insurance does not disapprove the transaction within 30 days following receipt by the Department of Banking and Insurance of the additional information as requested, the transaction shall be deemed approved.
- (j) No HMO shall pay out dividends except in accordance with N.J.S.A. 17:27A-4 and N.J.A.C. 11:1-35.

[Public Notice: Increase in medical component of the Consumer Price Index. See: 29 N.J.R. 2484(a).]

[Public Notice: Increase in medical component of the Consumer Price Index. See: 30 N.J.R. 1330(a).]

[Public Notice: Increase in medical component of the Consumer Price Index. See: 31 N.J.R. 801(a).]

[Public Notice: Increase in medical component of the Consumer Price Index. See: 32 N.J.R. 1259(a).]

[Public Notice: Increase in medical component of the Consumer Price Index, See: 33 N.J.R. 1145(a).]

[Public Notice: Increase in medical component of the Consumer Price Index. See: 34 N.J.R. 1556(b).]

8:38-11.2 Investments

Except as approved by the Commissioner of Banking and Insurance in accordance with N.J.S.A. 26:2J-5a(1) and (3), all investments of HMOs shall be subject to and in compliance with N.J.S.A. 17B:20-1 et seq.

8:38-11.3 Reserve liabilities

- (a) An HMO shall maintain at all times reserve liabilities in an amount sufficient to provide for:
- 1. All claims incurred, whether reported or unreported, which are unpaid and for which the HMO is or may become liable, including the expense of adjustment or settlement of those claims;
- 2. Continued health care services to members for which a consideration has been received, or a consideration is due but unpaid; and
- 3. Continued health care services under the HMO contract to members who, on the date of termination of the HMO contract, are confined in an inpatient facility until discharge from the facility.

8:38-11.4 Minimum deposits

- (a) In order to obtain a certificate of authority, every HMO shall deposit with the Commissioner of Banking and Insurance no less than \$300,000, adjusted annually by the CPI beginning on July 1, 1997 in accordance with N.J.A.C. 11:2-32, Custodial Deposits.
- (b) In order to maintain a certificate of authority, every HMO shall annually adjust the deposit specified in (a) above to equal 20 percent of its minimum net worth, except that such deposit shall be no less than \$300,000 and no more than \$1,000,000 (as the minimum and maximum amounts are adjusted by the CPI).
- (c) The deposit required by (a) above, adjusted in accordance with (b) above, shall be subject to the following:
- 1. The deposit shall be and remain an admitted asset of the HMO for purposes of determining net worth of the HMO.
- 2. The Commissioner of Banking and Insurance shall use the deposit for administrative costs directly attributable to the rehabilitation, conservation or liquidation of the HMO.
- 3. All interest and other investment income derived from the deposit made shall be paid to the HMO annually upon written request.
- 4. An HMO may withdraw the deposit, or any part thereof, after making a substitute deposit of cash, securities, or other instruments permissible under N.J.A.C. 11:2-32, of equal amount and value.
- (d) Every HMO shall, except as (d)4iii below may apply, maintain a deposit with the Commissioner of Banking and Insurance. The deposit shall be held in trust as a restricted asset to offset reserves required pursuant to N.J.A.C. 8:38-11.3(a)1. The deposit shall be made in accordance with N.J.A.C. 11:2-32 except that the HMO may request permission from the Commissioner to use a custodian other than the custodian appointed pursuant to N.J.A.C. 11:2- 32.3(a). Notwithstanding the requirements of N.J.A.C. 11:2-32.3(b), the securities deposited with the custodian may be those which constitute eligible investments for life insurance companies pursuant to N.J.S.A. 17B:20-1a.
- 1. The required deposit amount shall be the equivalent of 50 percent of the highest calendar quarterly premium of the most recent four quarters.
- i. The initial or incremental premium-based deposit due following June 21, 1999 may be payable over a two-year (two-deposit) period pursuant to a plan approved by the Commissioner. HMOs may request an additional maximum one- year extension. An extension request shall be in writing and filed with the HMO's quarterly report due March 1 of the second year of the two-year phase- in period. The Commissioner shall grant an extension if the HMO is determined to be in "hazardous financial condition" as that term is defined at N.J.A.C. 11:2-27.2.
 - ii. Recalculation of the deposit amount shall occur no more frequently than annually.

- 2. The deposit and the accumulated investment income thereof shall be and remain an admitted asset of the HMO for purposes of determining net worth of the HMO.
- 3. The Commissioner of Banking and Insurance shall use this deposit of the HMO for costs of rehabilitation and/or liquidation of the HMO.
- 4. An HMO may withdraw its deposit or any part thereof, subject to the prior written approval of the Commissioner of Banking and Insurance, if:
- i. A substitute deposit of cash, securities or other instruments permissible under paragraph (d) above is made of equal amount and value;
- ii. The fair market value of the deposit exceeds the amount required to be held on deposit determined in accordance with (d)1 above; or
- iii. The required deposit amount is reduced by the Commissioner of Banking and Insurance as a result of discontinuance or sale of a line of business.
- 5. All income from the deposit made shall be an asset of the HMO, and the HMO may withdraw the income from such deposit on an annual basis, if the deposit and accumulated investment income exceeds the amount required to be held on deposit, subject to the prior written approval of the Commissioner of Banking and Insurance.
- 6. The HMO shall record the dedicated reserve for accounting purposes as "Assets as Restricted Cash and Other Assets."
- (e) HMOs shall determine when incremental deposits are necessary (based on the most recently filed SAP annual financial report) to assure that the required amount of deposits are maintained and shall make any necessary incremental deposit annually by June 30.

8:38-11.5 Plan for continuation of services upon declaration of insolvency

- (a) In order to obtain and maintain a certificate of authority, an HMO shall submit a plan to the Commissioner and the Commissioner of Banking and Insurance, which assures continuation of services and benefits to members when the HMO is declared by a court of competent jurisdiction to be insolvent and placed in rehabilitation or liquidation.
- 1. Such plan shall assure the continuation of services and benefits to all members for the duration of the contract period for which premiums or other consideration has been paid and for any applicable grace period.
- 2. Such plan shall assure the continuation of services and benefits under the HMO contract to members who, on the date of the declaration of insolvency, are confined in an inpatient facility until their discharge from the facility, or their contractual benefits are otherwise exhausted, whichever occurs first.
- (b) In determining whether such a plan is acceptable for the issuance or continuance of a certificate of authority, the Commissioner and the Commissioner of Banking and Insurance may require one or more of the following:
- 1. The purchase of insurance by the HMO to cover the expenses to pay for continued covered benefits to members following a judicial declaration of the HMO's insolvency;
 - 2. Additional deposits;
 - 3. Acceptable letters of credit; and/or
 - 4. Other arrangements guaranteeing that benefits shall be continued.

8:38-11.6 Financial reporting requirements

- (a) Every HMO shall submit, no later than March 1, an annual report for the immediately preceding calendar year, completed as prescribed by the NAIC Annual Statement Instructions for Health Maintenance Organizations, and completed on a SAP basis, in accordance with the NAIC Accounting Practices and Procedures Manual, effective January 1, 2001, incorporated herein by reference, as amended and supplemented (NAIC, 2301 McGee Street, Kansas City, MO 64108).
- 1. HMOs shall submit the annual report for calendar year 1996 (reported in March 1997) and thereafter using the current format established for any year by the National Association of Insurance Commissioners for HMOs, more commonly referred to as the "NAIC blank" for HMOs, the forms of which are available for purchase through several independent insurance service companies throughout the United States.

- 2. Every HMO shall submit with the annual report a certification of and an opinion by a member of the American Academy of Actuaries or an active fellow of the Society of Actuaries that the reserves required by N.J.A.C. 8:38- 11.3 and included on the HMO's SAP annual report are sufficient.
- i. The actuarial certification shall identify the specific methodology used to determine the reserves, and shall specify whether and how the methodology has changed since the last report.
- ii. The workpapers prepared by the actuary in support of the certification shall be made available to the Department of Banking and Insurance upon request.
- (b) Every HMO shall submit, no later than June 1, audited annual financial reports for the immediately preceding calendar year for the HMO and any company that is a financial guarantor for the HMO, completed on a SAP basis; except that any financial guarantor that is not an insurer or HMO shall submit audited annual financial reports as set forth herein on a GAAP basis.
 - 1. The annual audited financial report shall include:
 - i. A report of an independent certified public accountant;
 - ii. A balance sheet reporting admitted assets, liabilities, capital and surplus;
 - iii. A statement of operations;
 - iv. A statement of cash flows;
 - v. A statement of changes in capital and surplus; and
- vi. Notes to financial statements in accordance with the NAIC Annual Statement Instructions.
- 2. The annual report shall be certified by an independent public accountant. The Commissioner of Banking and Insurance shall not recognize any person or firm as a qualified independent public accountant unless they are in good standing with the American Institute of Certified Public Accountants, and in all states in which the accountant is licensed to practice. Except as otherwise provided in this paragraph, an independent certified public accountant shall be recognized as qualified as long as he or she conforms to the standards of his or her profession, as contained in the Code of Professional Ethics of the American Institute of Certified Public Accountants and Rules and Regulations, Code of Ethics and Rules of Professional Conduct of the New Jersey Board of Public Accountancy or similar code.
- i. No partner or other person responsible for rendering a report may act in that capacity for more than seven consecutive years. Following any period of service, such person shall be disqualified from acting in that or a similar capacity for the same company for a period of two years. An HMO may make application to the Commissioner of Banking and Insurance for relief from the above rotation requirement on the basis of unusual circumstances. The Commissioner of Banking and Insurance may consider the following factors in determining if the relief should be granted:
- (1) The number of partners, expertise of the partners or the number of HMO clients in the currently registered firm; and
 - (2) The premium volume of the HMO;
- ii. The Commissioner of Banking and Insurance shall not recognize as a qualified independent certified public accountant, nor accept any annual audited financial report, prepared in whole or in part by, any natural person who:
- (1) Has been convicted of fraud, bribery, a violation of the Racketeer Influenced and Corrupt Organization Act, 18 U.S.C. §§ 1961 through 1968, or any dishonest conduct or practices under Federal or state law, or similar conduct under any foreign law;
- (2) Has been found to have violated the insurance laws of this State with respect to any previous reports submitted under this subchapter; or
- (3) Has demonstrated a pattern or practice of failing to detect or disclose material information in previous reports filed under the provisions of this subchapter.
- iii. Whenever it appears that the certified public accountant or accounting firm retained by the HMO to conduct the annual audit is not a qualified independent certified public accountant as provided under these rules, the Department of Banking and Insurance shall notify the HMO that it does not recognize the certified public accountant or accounting firm as qualified, and the Department of Banking and Insurance shall not accept any audited financial report prepared by that accountant or accounting firm. However, upon receipt of such notice from the Department of Banking and Insurance, the HMO may, within 20 days, request an administrative review on the issue of the qualifications of the independent certified public accountant or accounting firm retained by the HMO.

- 3. Any internal control letter prepared by the independent public accountant shall also be submitted with the annual report.
- 4. Each HMO required by this subchapter to file an annual audited financial report shall, within 60 days after becoming subject to such requirement, register with the Commissioner of Banking and Insurance in writing the name and address of the independent certified public accountant or accounting firm retained to conduct the annual audit. HMOs not retaining an independent certified public accountant on April 16, 2001 shall register the name and address of their retained certified public accountant not less than six months before the date when the audited financial report is to be filed.
- 5. The HMO shall also obtain a letter from the accountant, and file a copy with the Commissioner of Banking and Insurance, stating that the accountant is aware of the provisions of the HMO statutes, regulations, and administrative rules of this State that relate to accounting and financial matters. The accountant shall also certify that he or she will express his or her opinion on the financial statements in the terms of their conformity to the statutory accounting practices prescribed or otherwise permitted by the Department of Banking and Insurance and specify such exceptions as he or she may believe appropriate.
- 6. In addition to the requirements in (b)4 and 5 above, if the accountant for the immediately preceding filed audited financial report is dismissed or resigns, the HMO shall, within five business days, notify the Department of Banking and Insurance of this event. The HMO shall also furnish the Commissioner of Banking and Insurance with a separate letter within 10 business days of the above notification stating whether in the 24 months preceding such event there were any disagreements with the former accountant on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure; which disagreements, if not resolved to the satisfaction of the former accountant, would have caused him or her to make reference to the subject matter of the disagreement in connection with his or her opinion. The disagreements required to be reported in response to this paragraph include both those resolved to the former accountant's satisfaction and those not resolved to the former accountant's satisfaction. Disagreements contemplated by this paragraph are those that occur at the decision-making level (that is, between personnel of the HMO responsible for presentation of its financial statements and personnel of the accounting firm responsible for rendering its report). The HMO shall also request in writing that such former accountant furnish a letter addressed to the HMO stating whether the accountant agrees with the statements contained in the HMO's letter and, if not, stating the reasons for which he or she does not agree; and the HMO shall furnish such responsive letter from the former accountant to the Commissioner of Banking and Insurance together with its own.
- (c) Every HMO shall submit, no later than March 1 annually, the New Jersey- Specific Annual Supplement, available from either the Department of Banking and Insurance or the Department of Health and Senior Services, for the preceding calendar year.
- (d) Every HMO shall submit quarterly reports no later than 45 days following the close of each of the first three calendar quarters (that is, May 15, August 15, and November 15, respectively), completed as prescribed by the NAIC Annual Statement Instructions for Health Maintenance Organizations, and completed on a SAP basis, in accordance with the NAIC Accounting Practices and Procedures Manual.
- 1. HMOs shall submit the quarterly report using the NAIC blank for HMOs in effect at the time of the quarter reported.
- 2. The quarterly reports shall also include "Membership by County," and "Analysis of Minimum Net Worth Requirements" of the New Jersey-Specific Annual Supplement, and any other data requested of a particular HMO by the Commissioner or the Commissioner of Banking and Insurance, attached to the last page of the guarterly report.
- 3. Every HMO shall submit with the quarterly financial report a certification of, and an opinion by, a member of the American Academy of Actuaries or an active fellow of the Society of Actuaries that the reserves required by N.J.A.C. 8:38-11.3 and included on the HMO's annual report are sufficient.
- i. The actuarial certification shall identify the specific methodology used to determine the reserves, and shall specify whether and how the methodology has changed since the last report.
- ii. The workpapers prepared by the actuary in support of the certification shall be made available to the Department of Banking and Insurance upon request.
- 4. The quarterly reports shall include a certification identifying all of the HMO's current reinsurance, insolvency and stop loss insurance arrangements, which shall include the identity of all reinsurers and insurers, policy periods, appropriate deductibles and coverage limits, the face page of all inforce policies, and a statement as to whether any of these risks are self- funded.

- (e) Both the NAIC blank and the New Jersey--Specific Annual Supplement, including those sections required to be completed on a quarterly basis, shall be completed in their entirety; if a specific schedule is not applicable to the HMO, that should be so indicated using "N/A" or "None".
- (f) With respect to completion of the New Jersey-Specific Annual Supplement, if an HMO's actual net worth calculated in "Analysis of Minimum Net Worth Requirements" of the New Jersey-Specific Annual Supplement for the reporting period is less than 125 percent of the required minimum net worth for the HMO as required pursuant to N.J.A.C. 8:38-11.1, the HMO shall include with its then-current report a detailed plan of action demonstrating how the minimum net worth shall be maintained, specifying marketing and financial projections.
- 1. The plan of action shall include documentation of supporting assumptions made by the HMO.
- 2. The plan of action shall include discussions of alternate funding sources and shall specifically discuss parental or affiliate guarantees.
- 3. The plan of action shall be subject to review and approval of the Commissioner of Banking and Insurance.
- (g) With respect to completing the annual and quarterly SAP reports, periodic interim payments (PIP) from Medicaid managed care organizations to financially distressed hospitals as approved by the Division of Medical Assistance of the Department of Human Services shall be considered admitted assets, provided the amounts advanced are settled within 90 days.
- (h) The annual and quarterly Revenue and Expense Statements (Report #2-NAIC) shall include separate supplemental pages for "Commercial only," "Medicare," "Medicaid" and any other publicly funded program.
- (i) Annual and quarterly reports shall not be accepted unless completed in accordance with this subchapter and additional instructions that may be obtained from the Department of Banking and Insurance at the address specified at (j) below.
 - (j) Every HMO shall submit three copies each of its reports to:

Chief Insurance Examiner
Office of Financial Examinations
N.J. Department of Banking and Insurance
20 West State Street
PO Box 325
Trenton, NJ 08625-0325;

and two copies each to:

Director

N.J. Department of Health and Senior Services
Office of Managed Care
John Fitch Plaza
PO Box 360
Trenton, NJ 08625-0360

(k) Every HMO that has a contract with the Department of Human Services to provide coverage to the Medicaid population, or some segment thereof, also shall submit one copy of its reports to:

Executive Director
Office of Managed Health Care
Division of Medical Assistance and Health Services
N.J. Department of Human Services
Quakerbridge Plaza, Building 5
PO Box 712
Trenton, NJ 08625-0712

8:38-11.7 Reporting of compensation arrangements with health care providers involving incentive or disincentive programs

- (a) In conjunction with the submission of the New Jersey--Specific Annual Supplement made in accordance with N.J.A.C. 8:38-11.6(c), every HMO shall submit aggregate reports on compensation arrangements between the HMO and providers under contract with the HMO (directly or through a secondary contractor) using the edition of HEDIS Table XIX (Primary Care Physician Payment Arrangement), Table XX (Specialist Payment Arrangement), and Table XXI (Mental Health Provider Payment Arrangement) for Medicaid in effect at the time of submission. Such tables are available from the National Commission on Quality Assurance, 1350 New York Avenue, Suite 700, Washington, DC 20005.
- 1. An HMO operating multiple lines of business (Medicaid, Medicare, and commercial, including any administrative service only business unless the health care providers have contracted with the self-funded arrangement) shall submit information separately for Medicaid, Medicare and commercial business if the HMO has different compensation arrangements for these lines of business.
- (b) In conjunction with the submission of the New Jersey--Specific Annual Supplement made in accordance with N.J.A.C. 8:38-11.6(c), every HMO that uses financial incentive or disincentive arrangements in its compensation packages with providers under contract with the HMO (directly or through a secondary contractor) and/or utilization review organizations shall provide a certified explanation as to their accounting of the financial incentive or disincentive arrangements on the forms prescribed by the Commissioner of Banking and Insurance completed in accordance with the instructions for those forms pursuant to N.J.A.C. 8:38-11.6(h).
 - 1. The explanation shall be certified to by the Chief Financial Officer of the HMO.

8:38-11.8 Rating

- (a) Prior to issuing or amending any contracts for coverage, an HMO shall submit a certification, including an actuarial opinion certified by a member of the American Academy of Actuaries or an active fellow of the Society of Actuaries, for filing with the Commissioner of Banking and Insurance demonstrating that the rates to be used by the HMO are not excessive, inadequate or unfairly discriminatory (except as (a)1 below applies), specifying the rating methodology the HMO shall use.
- 1. Except as (a)2 below may apply, the Commissioner of Banking and Insurance shall find that a filing that uses one of the three following rating methodologies produces rates that are not unfairly discriminatory without

further actuarial certification or demonstration:

- i. Community rating that does not consider the age, gender, geography, occupation or health status of any specific member covered under a contract form when determining premiums of that specific member;
- ii. Community rating by class that does not take into consideration the health status of any specific member covered under a contract form when determining premiums for that specific member; or
- iii. Prospective experience rating by group that does not take into consideration the health status of a covered member of a specific (employment-based) group when determining premiums for that specific member, but which does segregate the group's health history and claims experience from other groups covered under the same contract form for purposes of establishing premiums for the group on a prospective basis.
- 2. Notwithstanding (a)1 above, every HMO shall comply with N.J.S.A. 17B:27A-2 et seq. and 17B:27A-17 et seq. when establishing rating methodologies for their individual and small employer group contracts.

8:38-11.9 (Reserved)

SUBCHAPTER 12. REHABILITATION, CONSERVATION AND LIQUIDATION

8:38-12.1 Rehabilitation, conservation and liquidation generally

- (a) An HMO shall cease new enrollment, except for addition of family members of current members, upon receipt of notice of the filing of a petition by the Commissioner of Banking and Insurance for an order authorizing rehabilitation of the HMO pursuant to N.J.S.A. 17B:32-31 et seq., Life and Health Insurers Rehabilitation and Liquidation Act, if enrollment has not ceased prior to that date, until such time as the petition may be denied.
- (b) Participating health care providers, whether or not subject to a total or partial hold harmless provision of their participation contract with the HMO, and nonparticipating health care providers incurring expenses for rendering services to the HMO's members that are covered within the terms of the HMO's contract with the member shall have class 3 claims against the HMO as specified in N.J.S.A 17B:32-71 (which follow the class 3 claims of members or subscribers and their beneficiaries), and shall not bill or otherwise pursue any legal action against a member of an HMO against whom an order or rehabilitation of liquidation has been issued.
- (c) Neither the reformation of member or provider contracts, restructuring of liabilities, or transfer of all or a portion of the HMO's business to another HMO that may occur in the course of the rehabilitation or liquidation of an HMO shall alter the applicability of (a) or (b) above unless the Commissioner of Banking and Insurance or a court of competent jurisdiction specifically orders that (a) or (b) or both be altered so as to facilitate the reformation, restructuring or transfer of business.

8:38-12.2 Alternate methodology for assuring continuation of services to HMO members

- (a) The Commissioner of Banking and Insurance may order carriers and other HMOs to offer the members of an insolvent HMO an opportunity to become insured or to enroll with the carriers and other HMOs, during no less than a 30-day open enrollment period to be determined by the Commissioner of Banking and Insurance, except as (b) below may apply.
- 1. If more than a single choice was offered to the members of a group during the group's last regular enrollment period, the Commissioner of Banking and Insurance's order shall be limited to those carriers and HMOs that participated in the enrollment process with the insolvent HMO during the group's last regular enrollment period, except that if the Commissioner of Banking and Insurance determines that the other HMOs and/or managed care plans of the carriers that participated with the insolvent HMO lack sufficient capacity to assure that health care services shall be available and accessible to the group's members, then the Commissioner of Banking and Insurance may order all HMOs operating within the same service areas as the insolvent HMO to enroll an equitable portion of the insolvent HMO's members, as determined by the Commissioner of Banking and Insurance.
- i. Carriers and HMOs that participated with the insolvent HMO at the group's last regular enrollment period shall offer the members of the insolvent HMO the same coverage at the same rates that the carriers and HMOs offered to the group's members at the group's last regular enrollment period, which shall be effective until the group's regular renewal period.
- ii. HMOs that did not participate with the insolvent HMO at the group's last regular enrollment period shall offer the members of the insolvent HMO coverage that is most similar to the coverage the members have with the insolvent HMO, as determined by the Commissioner of Banking and Insurance, at the successor HMO's then-current rates for the coverage offered.
- 2. When the members of the insolvent HMO are not members of a group, or are members of a group that did not have multiple choices of carriers or HMOs with whom to become insured or enrolled during the group's last regular enrollment period, the Commissioner of Banking and Insurance may order that all HMOs within the service area of the insolvent HMO shall enroll an equitable portion of the insolvent HMO's members, as determined by the Commissioner of Banking and Insurance.
- i. The successor HMO shall offer the members of the insolvent HMO coverage that is most similar to the coverage the members have with the insolvent HMO, at the successor HMO's then-current rates for the coverage offered.
- 3. In allocating members to other HMOs, the Commissioner of Banking and Insurance shall consider the capacity of the HMOs to assure that health care services will be available and accessible to the members.

- (b) The Commissioner of Banking and Insurance shall act in consultation with the Director of the Division of Medical Assistance and Health Services in allocation of Medicaid members of an insolvent HMO.
- (c) With respect to Medicaid recipients and Medicare beneficiaries who are members or other members under special State government contracts, such members of an insolvent HMO shall only be allocated to HMOs within the same service area as the insolvent HMO that have a similar contract with the Medicare, Medicaid or other special State government programs.
- (d) With respect to members under standard individual health benefits plans or members who are members of small employer groups as defined by N.J.S.A. 17B:27A-17 et seq., such members of an insolvent HMO shall only be allocated to HMOs within the same service area as the insolvent HMO that have elected to offer coverage to individuals and members of small employer groups.

SUBCHAPTER 13. LICENSING OF REPRESENTATIVES AND ADVERTISING

8:38-13.1 General applicability of producer licensing requirements

- (a) Except as (e) below or N.J.A.C. 8:38-13.2 may apply, no HMO shall employ, directly or indirectly, any person to solicit, negotiate or bind contracts for the delivery to subscribers or members of health care services through an HMO, or to communicate with subscribers or members concerning the terms and conditions of such a contract, or to establish or administer office management practices affecting subscribers or members, or to process claims, or to transmit funds between subscribers or members, producers, premium finance companies, insurance companies or the HMO unless such person is licensed as an insurance producer in New Jersey in accordance with N.J.A.C. 11:17, Producer Licensing, and the HMO has complied with the specific requirements of N.J.A.C. 11:17-2.9.
- 1. An HMO shall contract only with an insurance producer who has completed the educational requirements prescribed at N.J.A.C. 11:17-3 and is licensed as an insurance producer with a health authority.
- 2. Those persons whose duties are clerical in nature shall not be required to be a licensed producer. Clerical duties are those administrative tasks accomplished in the office and under the supervision of the HMO or a licensed producer that are necessary to produce the contract for health services in accordance with the HMO's or producer's normal procedures and systems, including but not limited to, those functions incorporated under the definition of clerical duties at N.J.A.C. 11:17A-1.2.
- 3. Those persons who are in the employ of the HMO whose income from his or her employ with the HMO is not dependent, in whole or in part, upon commission shall not be required to be licensed as a producer unless such person's duties with the HMO include soliciting, negotiating or binding contracts with subscribers or members.
- (b) Every person under contract with or employed by an HMO who is required to be licensed as an insurance producer shall comply with the provisions of N.J.S.A. 17:22A-1 et seq., and rules promulgated thereunder, including but not limited to the continuing education requirements of N.J.A.C. 11:17, 11:17A, Market Conduct, 11:17B, Commissions and Fees, and 11:17C, Management of Funds, as appropriate for any producer licensed with a health authority.
- (c) Every person under contract with or employed by an HMO who is required to be licensed as an insurance producer shall be subject to action by the Commissioner of Banking and Insurance in accordance with N.J.S.A. 17:22A-17 and N.J.A.C. 11:17D, Administrative Procedures and Penalties.
- (d) An HMO and its employees or ther representatives who perform functions set forth at (a) above who are not licensed as an insurance producer on July 1, 1997 shall be permitted to come into compliance with the requirements of this subchapter by July 1, 1998, and shall not be subject to penalty or fine for the performance of those functions set forth at (a) above within that one year period, if the HMO and the person are making a good faith effort to comply with this subchapter. Good faith shall be demonstrated upon the written request of the Department of Banking and Insurance and may include, but is not necessarily limited to, demonstrations of the following:
- 1. Proof of registration in one or more prelicensing courses by January 1, 1998, or application for a waiver of the prelicensing requirements, as specified at N.J.A.C. 11:17-3.2, with respect to persons who are not licensed as producers.
- 2. Proof of registration by September 29, 1997 for continuing education courses with respect to those persons who may be licensed as producers, but who had not intended to retain their license while in the employ of or working under contract with the HMO, and who are otherwise lacking in the required continuing education credits necessary to maintain their license on the effective date of this subchapter.

8:38-13.2 Medicaid marketing representatives

(a) Notwithstanding N.J.A.C. 8:38-13.1, an HMO under contract with the Division of Medical Assistance and Health Services of the New Jersey Department of Human Services to enroll Medicaid recipients shall register its marketing representatives employed solely for the purpose of enrolling Medicaid recipients in accordance with N.J.A.C. 11:17-2.11 as Medicaid marketing representatives, unless such person is an insurance producer and is appointed by the HMO as its agent pursuant to N.J.A.C. 8:38-13.1.

(b) An HMO shall register each Medicaid marketing representative with the Department of Banking and Insurance in accordance with N.J.A.C. 11:17-2.11 prior to the representative commencing any marketing activities. Any HMO already enrolling Medicaid recipients using persons who are not licensed insurance producers as required pursuant to N.J.A.C. 8:38-13.1 on July 1, 1997 shall register such persons as Medicaid marketing representatives (if the HMO does not otherwise intend to comply with N.J.A.C. 8:38-13.1 with respect to its Medicaid business) by September 29, 1997 and shall otherwise comply with this chapter. Registrations shall be sent to the following:

Attn: License Processing
New Jersey Department of Banking and Insurance
20 West State Street
CN 327
Trenton, NJ 08625

- (c) Every HMO that uses or intends to use Medicaid marketing representatives shall submit to the Departments of Health and Senior Services, Human Services and Banking and Insurance, at the addresses specified at N.J.A.C. 8:38- 11.6(i) and (j), a pre-registration training program for Medicaid marketing representatives.
- 1. The materials submitted shall include the form the HMO shall issue to Medicaid marketing representatives evidencing satisfactory completion by the Medicaid marketing representative of the HMO's pre-registration training program.
- 2. An HMO enrolling Medicaid recipients with persons not registered as either insurance producers or as Medicaid marketing representatives on the effective date of this subchapter shall submit a pre-registration training program no later than September 29, 1997.
- (d) Every HMO shall submit for filing with the Departments of Health and Senior Services, Human Services and Banking and Insurance a description of the organizational structure involving the marketing of the Medicaid product, which shall include an explanation of the method by which the HMO shall supervise the Medicaid marketing representatives and evaluate their effectiveness.
- (e) Every HMO shall assure the continued education of Medicaid marketing representatives in the manner set forth in this subsection.
- 1. The HMO shall develop or otherwise arrange for continuing education programs for Medicaid marketing representatives, with programs available no less than semiannually.
- 2. The HMO shall submit a description of its continuing education program to the Departments of Health and Senior Services, Human Services and Banking and Insurance by August 30, 1997 or within 60 days following the date that it first registers Medicaid marketing representatives, whichever date is later.
- i. Submission of a description of a continuing education program by an HMO in accordance with (e)2 above shall in no way serve as a substitute for the submission and approval process set forth for the continuing education requirements of N.J.A.C. 11:17-3.4.
- 3. Submissions shall be made to the addresses set forth at N.J.A.C. 8:38- 11.6(i) and (j) with respect to the Departments of Banking and Insurance and Human Services.
- (f) Every HMO shall maintain records for each Medicaid marketing representative specifying the registration of the Medicaid marketing representative, certification of completion of all initial and continuing education programs, and a copy of the notice of termination of registration filed with the Department of Banking and Insurance, which records shall be available for inspection by the Departments of Health and Senior Services, Human Services and Banking and Insurance within a reasonable time following request.
- 1. HMOs shall maintain records of terminated Medicaid marketing representatives for no less than three years following the date of termination of their registration.
- (g) The requirements set forth in this section are in addition to any standards and requirements which may be established by the Department of Human Services for the Medicaid program.
- (h) The requirements set forth herein in this section in addition to the requirements of N.J.A.C. 11:17-2.9.

8:38-13.3 Advertising and marketing

Except to the extent that HMOs shall be specifically exempted by reference by a provision of an applicable statute or rule, HMOs, producers and Medicaid marketing representatives shall comply with statutes and rules regulating the marketing, advertising, solicitation and sale of health insurance, and enforcement thereof by the Commissioner of Banking and Insurance, including, but not limited to, N.J.A.C. 11:2-11 and 11:4-17.

8:38-13.4 Disclosure of provider compensation arrangements

- (a) HMOs shall make the following disclosure statements, as applicable, in all applications for enrollment and member handbooks:
 - 1. Every HMO shall make the following disclosure:

"[Different] providers in our network have agreed to be paid [in different ways by us. Your provider may be paid] [each time s/he treats you ("fee for service")][, or may be paid] [a set fee each month for each member whether or not the member actually receives services ("capitation")][, or may receive] [a salary]."

2. The HMO shall add the following statement if the HMO contracts directly or indirectly with providers to participate in financial incentive arrangements (for example, this includes financial incentive arrangements between an intermediate entity and a physician or physician group):

"These payment methods may include financial incentive agreements to pay some providers more ("bonuses") or less ("withholds") based on many factors: member satisfaction, quality of care, and control of costs and use of services among them."

3. Each HMO shall make the following statement:

"If you desire additional information about how our primary care physicians or any other provider in our network are compensated, please call us (or carrier name) at (telephone number) or write (address)."

4. Every HMO shall make the following statement:

"The laws of the State of New Jersey, at N.J.S.A. 45:9-22.4 et seq., mandate that a physician, chiropractor or podiatrist who is permitted to make referrals to other health care providers in which s/he has a significant financial interest inform his or her patients of any significant financial interest he or she may have in a health care provider or facility when making a referral to that health care provider or facility. If you want more information about this, contact your physician, chiropractor or podiatrist. If you believe that you are not receiving the information to which you are entitled, contact the Division of Consumer Affairs in the New Jersey Department of Law and Public Safety at (973) 504-6200 OR (800) 242-5846."

- (b) The HMO may propose alternate stylistic language for the statement in (a) above which may be utilized only with the prior written approval from both the Departments of Health and Senior Services and Banking and Insurance. Any modification must be written in plain language and cannot substantively alter the meaning and/or intent of the above section.
- (c) All statements are required in (a) and (b) above shall be prominently displayed and printed in at least the same point and print as used for other material contained in the application and handbook other than captions or headings.
- (d) HMOs shall be required to provide information in response to requests made pursuant to the disclosure requirement set forth in (a) above with respect to provider compensation by disclosing the method by which a specific provider is compensated. An HMO shall not be required to state the dollar

amount of compensation or otherwise provide more specific information about the compensation arrangement it has with a specific provider.

(e) HMOs shall provide a copy of this revised disclosure statement to all prospective members beginning June 30, 2000, and shall provide the revised statement to all current members no later than the anniversary date of the contract under which the member is covered first occurring on or after June 30, 2000.

8:38-13.5 Trade and claims practices and coordination of benefits

- (a) HMOs shall be subject to all of the provisions of the Trade Practice Act, N.J.S.A. 17B:30-1 et seq., any amendments thereto, and all rules promulgated thereunder, except to the extent that HMOs have been specifically excluded by reference from a provision of the applicable statutes or rules.
- (b) HMOs that elect to coordinate their benefits with those of other benefits or coverages available to members may do so subject to compliance with N.J.A.C. 11:4-28, Coordination of Benefits. HMOs that do not comply with N.J.A.C. 11:4-28 shall provide primary coverage to all members.

8:38-13.6 Penalties

Every producer or Medicaid marketing representative found to be in violation of this subchapter shall be subject to penalties and fines (per contract) in accordance with N.J.A.C. 11:17D, including suspension or revocation, in whole or in part, of his or her producer license or registration privilege pursuant to N.J.S.A. 17:22A-17.

SUBCHAPTER 14. INDEMNITY BENEFITS OFFERED BY A HEALTH MAINTENANCE ORGANIZATION

8:38-14.1 Purpose, scope and applicability

- (a) The purpose of this subchapter is to set forth the standards by which HMOs shall offer and deliver a contract for a point of service product in New Jersey.
- (b) This subchapter applies to all HMOs authorized to transact business in this State for the purposes of providing health care services in accordance with N.J.S.A. 26:2J-1 et seq.

8:38-14.2 Requirement to offer a point of services contract

- (a) An HMO shall offer a point of service product in this State that allows a member to receive covered services from an out-of-network health care professional without obtaining a referral or prior authorization from the HMO, except if:
 - 1. Its only members are Medicaid recipients;
 - 2. It is a Federally-qualified, nonprofit HMO; or
- 3. The HMO is affiliated with an insurance company or health service corporation that offers a contract or policy for delivery in this State in conjunction with a selective contracting arrangement approved in accordance with N.J.A.C. 11:4-37, Selective Contracting Arrangements, and that policy or contract allows a covered person to receive services covered under the policy or contract or receive payment of benefits therefor from providers not in the insurance company's or health service corporation's network of participating providers without obtaining a referral or prior authorization from the insurance company or health service corporation.
- i. In addition to (a)3 above, the insurance company or health service corporation shall provide subscribers under a group health plan in which the contractholder offers one of the insurance company's or health service corporation's contracts or policies provided in conjunction with a selective contracting arrangement an opportunity to elect coverage under the contract(s) or policy(ies) provided in conjunction with a selective contracting arrangement on at least an annual basis following a written notice to the subscribers setting forth the details of the contract(s) and policy(ies) provided in conjunction with the selective contracting arrangement.
- (b) An HMO that meets the exceptions of (a) above shall not be required to offer any point-of service contract.
- (c) An HMO that fails to meet the exceptions of (a) above shall not be required to offer more than one point-of-service contract meeting the standards of (a) above so long as the point-of-service contract offered in compliance with (a) above is available to all group contract holders.
- (d) An HMO that fails to meet the exceptions of (a) above shall not be required to offer any other point-of-service contracts, so long as the HMO complies with (c) above.

8:38-14.3 General standards

- (a) Except as set forth in (b) below, an HMO shall not enter into any arrangement for the provision of out-of-network covered services to any subscriber or member that is not in compliance with this subchapter.
- (b) An HMO providing out-of-network covered services under an arrangement approved by the Department of Banking and Insurance on or before April 15, 1996 shall bring the arrangement and any contracts issued under that arrangement into compliance with this subchapter beginning on the first 12 month anniversary date of each of the subscriber contracts occurring on or after October 12, 1996.
- (c) An HMO shall not offer or provide any POS contract to groups of 50 or more until the form of that contract, along with applicable evidence of coverage forms, has been filed and approved or deemed approved, by the Department and the Department of Banking and Insurance; an HMO shall not offer or provide a POS contract by rider, amendment or endorsement of any HMO contract.
- 1. If not disapproved within 60 days of the date of receipt by the Departments, the form shall be deemed filed, if not affirmatively approved prior thereto.
- 2. Disapproval of the form shall be in writing, and shall specify the reasons for the disapproval.

- 3. An HMO whose form has been disapproved shall have 60 days following the date of the initial disapproval within which to correct any deficiencies set forth in the notice of disapproval, and shall have 30 days following the date of notice of any subsequent disapproval within which to correct deficiencies. A resubmission of a form shall be deemed approved upon the expiration of 30 days following resubmission of the filing to the Department and the Department of Banking and Insurance unless the Departments approve or disapprove the resubmission within the 30 day period.
- 4. If an HMO does not respond to a notice of disapproval within the required time frame, the matter shall be considered closed by the Departments; if the HMO desires further consideration of its form, it shall submit the form anew to the Department and the Department of Banking and Insurance.
- (d) Contemporaneous with the submission of the POS contract form, the HMO shall make an informational rate filing with the Department of Banking and Insurance meeting the requirements of this subchapter.
- (e) Submission of forms and rates to the Department of Banking and Insurance shall be made to (and accompanied by the appropriate service fee, if any, specified at N.J.A.C. 11:1-32):

Managed Care Bureau
Life and Health Division
New Jersey Department of Banking and Insurance
PO Box 325
20 West State Street
Trenton, NJ 08625-0325

- (f) The requirements of this subchapter shall be in addition to, and not in lieu of, more specific standards that may be established for compliance with the Individual Health Coverage Program, N.J.S.A. 17B:27A-2 et seq., and the Small Employer Health Benefits Program, N.J.S.A. 17B:27A-17 et seq., and rules promulgated pursuant thereto.
- (g) At least one of the POS products offered by an HMO shall permit members to receive covered services out-of-network without being required to obtain a referral or prior authorization to go to an out-of-network health care professional from the HMO, except as N.J.A.C. 8:38-14.2(a)1, 2 or 3 applies.
- 1. In the instance in which the required POS contract is held by a group contract holder, the HMO shall provide members under the contractholder's group health plan an opportunity to elect coverage under the required POS contract(s) at least annually following the dissemination of written notice to the members detailing the POS contract.
- (h) The HMO shall maintain an adequate network for its POS contracts, pursuant to N.J.A.C. 8:38-5, to assure that members are able to access services in- network and take full advantage of the innetwork benefit levels.

8:38-14.4 Out-of-network benefit restriction under an HMO POS contract with a reinsurance-type or group master policy arrangement

- (a) An HMO may offer a POS contract with or without a gatekeeper system for out-of-network covered services, except that any POS contract offered without a gatekeeper system for out-of-network covered services shall meet the following:
- 1. The deductible for the out-of-network covered services shall be no less than \$250.00 per person per benefit period, or \$500.00 per family per benefit period, and the coinsurance requirement shall be no less than 20 percent for the next \$5,000 of covered charges for covered services per individual per benefit period, and no less than 20 percent for the next \$10,000 of covered charges for covered services per family per benefit period; or
- 2. The deductible and coinsurance requirements are otherwise designed so that, in combination, there is a substantial disincentive to accessing out-of- network covered services, as determined satisfactory to the Commissioner of Banking and Insurance, consistent with (a)1 above.
- (b) Notwithstanding that an HMO elects to utilize a gatekeeper system for out- of-network covered services, the HMO shall provide that the deductible and coinsurance requirements for the access of out-of-network covered services are otherwise designed so that, in combination, there is a reasonable, disincentive to accessing such out-of-network covered services, as determined satisfactory to the Commissioner of Banking and Insurance.

(c) Notwithstanding (a) and (b) above, the actuarial value of the out-of- network covered services shall not vary by more than 30 percent from the actuarial value of the in-network covered services under any POS contract, as further specified at N.J.A.C. 11:4-37.3(b)6.

8:38-14.5 POS under a reinsurance-type contract arrangement

- (a) The reinsurance-type contract shall cover the entire cost of the out-of- network covered services, and shall not provide for any deductible, coinsurance, copayment, or other type of mechanism by which any portion of the out-of-network covered services become self-funded by the HMO.
- 1. The HMO may elect not to include benefits for emergency and out-of-area care under the reinsurance-type contract.
- 2. If the HMO elects to include benefits for emergency and out-of-area care under the reinsurance-type contract, the HMO and the carrier or insurer may specify a deductible or other mechanism by which the HMO shall self-fund some portion of the emergency and/or out-of-area care benefits only.
- (b) The reinsurance-type contract shall include a provision by which the carrier or insurer agrees to indemnify members directly, subject to the terms of the HMO's contract with its subscribers and contractholders, if the HMO is placed into conservation, rehabilitation or liquidation.
- (c) The reinsurance-type contract shall be specific to the HMO's POS contract(s); stop loss or excess risk insurance, insolvency insurance, general letters of guaranty by parent or affiliate corporations and similar such forms of insurance and guarantees shall not be considered acceptable reinsurance-type contracts in compliance with this subchapter.
- (d) An HMO shall not report the reinsurance-type contract as an offset to its reserves for out-of-network covered services unless the carrier or insurer from whom the reinsurance-type contract is purchased and the transaction meet the requirements of N.J.A.C. 11:2-28, Credit for reinsurance.
- (e) The informational rate filing shall specify the premium and premium rating methodology for all services covered under the POS contract, including the cost to the HMO of purchasing the reinsurance-type contract to provide indemnity benefits for the out-of-network covered services.
- (f) Every reinsurance-type contract shall be submitted on an informational basis to the Department of Health and Senior Services and the Department of Banking and Insurance prior to the date of marketing of any POS contract for which the reinsurance-type contract is being purchased.
- 1. The POS contract and evidence of coverage submitted pursuant to N.J.A.C. 8:38-14.3 (b) or (c) shall be disapproved if the reinsurance-type contract fails to properly reflect the provisions of this subchapter or otherwise does not reflect a transfer of risk for the cost of the out-of- network services from the HMO to the reinsurer.

8:38-14.6 POS under a group health contract master policy arrangement

(a) The master policy form, certificate form and any other form that becomes a part of the group health contract, as applicable, shall be submitted by the carrier in duplicate in accordance with N.J.S.A. 17B:27-26 et seq., 17:48-1 et seq., 17:48A-1 et seq., or 17:48E-1 et seq., and N.J.A.C. 11:4-40, for filing to:

Health Bureau
Life and Health Division
New Jersey Department of Banking and Insurance
PO Box 325
20 West State Street
Trenton, NJ 08625-0325

- (b) The master policy form shall comply with all applicable insurance laws in this State.
- (c) The master policy form and certificate form shall clearly indicate that the contract shall be used in conjunction with an HMO service contract, wherein the group policyholder is an HMO and the insureds are a class of HMO subscribers and members.
- (d) The master policy shall provide indemnity benefits for all of the out-of- network covered services, except that the HMO and carrier may elect not to insure the HMO's emergency and out-of-area care through the master policy.

- (e) The POS contract and evidence of coverage shall specify all of the covered services under the POS contract, clearly indicating when services covered vary between the network and out-of-network covered services (for instance, due to differences between mandates between HMOs and carriers).
- (f) The certificate to be delivered to HMO members and the evidence of coverage to be delivered to HMO members may be contained in a single document, in which instance, the document shall be submitted by the HMO to the Managed Care Bureau of the Department of Banking and Insurance, and the carrier shall include a statement in its form submission to the Health Bureau of the Department of Banking and Insurance that the certificate shall be combined with the evidence of coverage and shall be submitted by the HMO in accordance with this subchapter, which statement shall be certified to by a duly authorized officer of the carrier.
- (g) The informational rate filing submitted by the HMO shall specify the premium and premium rating methodology for all services covered under the POS contract, including the cost to the HMO of purchasing the master policy to provide indemnity benefits for the out-of-network covered services.

8:38-14.7 POS under a dual contract arrangement

- (a) No HMO shall enter into a dual contracting arrangement until both the HMO contract forms and rates thereof and the indemnity policy forms and rates thereof, as applicable, have been submitted to the Department of Banking and Insurance for filing, each with unique identifying numbers for the dual contract arrangement product; neither riders, amendments nor endorsements of an HMO contract or an indemnity policy shall be filed for use as a dual contracting arrangement.
- (b) An indemnity policy designed to provide benefits for out-of-network covered services in conjunction with an HMO's network-based arrangement shall be subject to the following:
- 1. The policy form shall specify that it shall be issued and delivered in conjunction with an HMO contract, and shall contain reciprocal language incorporating the other contract;
 - 2. The policy form shall not be designed, nor shall it be offered, as a stand-alone policy;
 - 3. The policy form shall require execution of the indemnity policy by the contractholder; and
- 4. The policy form, application, certificate and other documents that make up the contract, as well as the rating formula, shall be filed by the Department of Banking and Insurance as required by N.J.S.A. 17B:27-49, 17:48-1 et seq., 17:48A-1 et seq., or 17:48E-1 et seq. and N.J.A.C. 11:4-40, as appropriate for the carrier.
- (c) An HMO contract designed to provide services on a network-based arrangement in conjunction with a carrier's indemnity policy shall be subject to the following:
- 1. The contract form shall specify that it shall be issued and delivered in conjunction with an indemnity policy, and shall contain reciprocal language incorporating the other contract;
 - 2. The contract form shall not be designed nor offered as a stand-alone contract;
 - 3. The contract form shall require execution of the HMO contract by the contractholder; and
- 4. The contract form, application, certificate and other documents that make upon the contract, as well as the rating formula, shall be submitted to the Department and the Department of Banking and Insurance for filing, and the forms shall not be used until so filed by the Department and Department of Banking and Insurance.
- (d) The HMO informational rate filing shall specify, by formula, the portion of the dual contract arrangement's full premium that shall be charged by the HMO for the network-based covered services; any modifications thereof shall be on a prospective basis only.
- (e) The carrier's rate filing, if a rate filing is required pursuant to statute, shall specify, by formula, the portion of the dual contract arrangement's full premium that shall be charged by the carrier for the out-of-network covered services.
- (f) Descriptive material (evidences of coverage, certificates, booklets) required to be provided to enrollees shall specify how both the HMO provisions and the indemnity provisions apply to the services and expenses covered under the dual contract arrangement.
- (g) The HMO shall submit a detailed description to the Department and the Department of Banking and Insurance specifying the responsibilities of the HMO and the carrier to one another, both administratively and financially, prior to implementation of any dual contracting arrangement. Arrangements established by an HMO and carrier to implement a dual contract that have the effect of violating the HMO or insurance laws of this State shall not be permitted.

8:38-14.9 (Reserved)

SUBCHAPTER 15. PROVIDER AGREEMENTS AND RISK TRANSFERENCE

8:38-15.1 Assumption of financial risk or risk-sharing

- (a) No person shall assume fnancial risk, in whole or in part, for the cost or provision of, or arrangements for, one or more health services to others unless the person is:
 - 1. An authorized payor as defined at N.J.A.C. 8:38-1.2;
- 2. A provider actually performing the health services (including providing supplies) within the scope of his or her license; or
 - 3. An employer with respect to its own employees, and dependents of those employees.
- (b) A secondary contract shall not be considered to have assumed financial risk for the delivery of health care services to residents of this State for which licensure as an authorized payor would otherwise be required if the secondary contractor enters into a contractual agreement with an authorized payor to provide the delivery of health care services to the individuals covered by the authorized payor which meets the requirements of N.J.A.C. 8:38-15.2 and 15.3
- (c) Contracts with secondary contractors shall not contain provisions that cede some or all of the financial risk of the authorized payor to the secondary contractors, whether through compensation formula, stop loss insurance requirements or other means, and an HMO shall not reduce its reserves or minimum net worth requirements on the basis of a contractual agreement with any secondary contractors.

8:38-15.2 Minimum standards for provider agreements

- (a) Both primary contractor and secondary contractor agreements shall be consistent with laws regarding confidentiality of information and with professional licensing standards, including, but not limited to, N.J.S.A. 45:14B-31 et seq., and shall comply with the standards of (b) through (e) below.
 - (b) All provider contracts with the HMO shall specify:
- 1. The term of the contract and reasons for which the contract may be terminated by one or more parties to the contract, including the procedures for notice and effectuation of such termination, and opportunities, if any to cure any deficiencies prior to termination, subject to the following:
- i. Provisions regarding notice of termination shall specify that if the contract is terminated prior to the contract's termination date, the HMO shall give the provider at least 90 days prior written notice; and, that in the event of such a termination, the provider has a right to request a hearing following such notice except when termination of health care professionals is based on: nonrenewal of the contract, a determination of fraud, breach of contract by the provider, or the opinion of the HMO's medical director that the provider represents an imminent danger to a patient or the public health, safety and welfare:
- ii. Provisions regarding contents of the notice of termination to be provided shall specify that the notice shall contain a statement as to the right of the provider to obtain a reason for the termination in writing from the HMO if the reason is not otherwise stated in the notice; the right of the provider to request a hearing, and any exceptions to that right; and, the procedures for exercising either right:
- iii. Provisions regarding the hearing shall specify the procedures for obtaining a hearing, and shall otherwise be consistent with the standards set forth at N.J.A.C. 8:38-3.6;
- iv. Provisions regarding the hearing shall include a statement that a provider's participation in the hearing process shall not be deemed to be an abrogation of the provider's legal rights; and
- v. Provisions regarding the right of the provider to request from the HMO the reasons for the termination shall specify the procedure for the provider to make the request, and that the HMO's reason in response to the request shall be in writing.
- 2. That no provider may be terminated or penalized solely because of filing a complaint or appeal as permitted by these rules;
- 3. That no provider may be terminated or penalized for acting as an advocate for the patient in seeking appropriate, medically necessary health services;
- 4. That a provider shall continue to provide services to members at the contract price following termination of the contract, in accordance with N.J.A.C. 8:38-3.5;

- 5. The method of reimbursement, including the method, events and timing of application of any penalties, bonuses or other types of compensation arrangements, subject to the following:
- i. The contract shall not provide financial incentives to the provider for the withholding of covered health care services that are medically necessary, but this shall not prohibit or limit the use of capitated payment arrangements between a carrier and provider.
- ii. To the extent that some portion of the provider compensation is tied to the occurrence of a pre-determined event, or the nonoccurrence of a pre-determined event, the event shall be clearly specified, and the HMO shall include in its contracts a right of each provider to receive a periodic accounting (no less frequently than annually) of the funds held.
- iii. The contract shall include a process whereby a provider may appeal a decision denying the provider additional compensation, in whole or in part, in accordance with any compensation arrangement tied to the occurrence or nonoccurrence of a pre-determined event.
- iv. Notwithstanding (b)5i above, capitation shall not be used as the sole method of reimbursement to providers who primarily provide supplies (for instance, prescription drugs or durable medical equipment) rather than services;
- 6. The services and/or supplies to be provided by the provider and for which benefits will be paid by the carrier;
- 7. A provision whereby the provider shall hold the covered person harmless for the cost of any service or supply for which the carrier provides benefits, whether or not the provider believes its compensation for the service or supply from the carrier (directly or through a secondary contractor) is made in accordance with the reimbursement provision of the provider agreement, or is otherwise inadequate.
- i. Members shall not be held harmless for payment of required copayments, deductibles or coinsurance, if any.
- ii. Providers shall not balance bill members who have obtained covered services or supplies through the HMO network mechanism.
- iii. An HMO's contractual agreement with a secondary contractor shall provide that the secondary contractor's contract with its network providers shall include a provision whereby the provider is required to hold the carrier's members harmless for the cost of any service or supply covered by the carrier, subject to (b)6i and ii above, whether or not the provider believes the compensation received is adequate;
 - 8. That providers shall not discriminate in their treatment of HMO patients;
- 9. That providers shall comply with the HMO's quality assurance and utilization review programs;
 - 10. That providers shall maintain licensure, certification and adequate malpractice coverage.
- i. With respect to a physician and dentist malpractice insurance shall be at least \$1,000,000 per occurrence and \$3,000,000 in the aggregate per year.
- ii. With respect to medical groups or health care facility providers, malpractice insurance shall be maintained at least in an amount determined sufficient for their anticipated risk, but no less than \$1,000,000 per occurrence and \$3,000,000 in the aggregate per year.
- iii. With respect to all other providers not otherwise under the auspices of a health care facility, malpractice insurance shall be maintained at least in an amount determined sufficient for their anticipated risk, but no less than \$1,000,000 per occurrence and \$3,000,000 in the aggregate per year;
- 11. That patient information shall be kept confidential, but that the HMO and the provider shall have a mutual right to a member's medical records, as well as timely and appropriate communication of patient information, so that both the providers and the HMO may perform their respective duties efficiently and effectively for the benefit of the member;
- 12. The process for an internal provider complaint and grievance procedure to be used by participating providers, pursuant to N.J.A.C. 8:38-3.7; and
- 13. That the provider shall have the right to communicate openly with a patient about all diagnostic testing and treatment options.
- (c) In addition to (b) above, all primary care provider contracts and contracts with specialists shall specify:
- 1. The responsibility, if any, of the provider with respect to acquiring and maintaining hospital admission privileges; and

- 2. The mutual responsibility of the provider and HMO to assure 24 hour, seven-day a week emergency and urgent care coverage to members, and the procedures to assure proper utilization of such coverage consistent with the requirements of N.J.A.C. 8:38-5.2.
 - (d) In addition to (b) above, all health care facility contracts shall specify:
- 1. The responsibility of the health care facility to follow clear procedures for granting of admitting and attending privileges to physicians, and to notify the HMO when such procedures are no longer appropriate;
 - 2. The admission authorization procedures for members;
 - 3. The procedures for notifying the HMO when members present at emergency rooms; and
 - 4. The procedures for billing and payment, schedules, and negotiated arrangements.
- (e) No contract with any provider shall impose obligations or responsibilities upon a provider which require the provider to violate the statutes or rules governing licensure of that provider if the provider is to comply with the terms of the contract.
- (f) n addition to (b) through (e) above, the contract between an HMO and a secondary contractor shall specify that the HMO is a third party beneficiary of the secondary contractor's contract(s) with the health care providers, and a secondary contractor's contract(s) with health care providers shall provide that the HMO shall have privity of contract with the health care providers such that the HMO shall have standing to enforce the secondary contractor's contract(s) with the health care providers in the absence of enforcement by the secondary contractor.
- (g) In lieu of (f) above, the HMO shall contract separately with each health care provider under contract with the secondary contractor, and such contracts shall be in accordance with (b) through (e) above.

8:38-15.3 Review and approval

- (a) The form(s) of the provider agreement(s), and any amendments thereto, shall be submitted to the Departments of Health and Senior Services and Banking and Insurance at the addresses specified at N.J.A.C. 8:38-11.6(i), for prior approval by the Department, following the receipt of comments from the Department of Banking and Insurance.
- (b) Provider agreements in effect upon May 1, 2000 shall be deemed withdrawn on May 1, 2001 if not in compliance with this subchapter.

8:38-15.4 Penalties

Every person acting as a secondary contractor in violation of this subchapter shall be subject to penalty and fine by the Department of Banking and Insurance under the insurance laws of this state as an unauthorized insurer in accordance with N.J.S.A. 17:51-1 et seq., or 17B:33-1 et seq., as may be appropriate.

(Reserved)

SUBCHAPTER 16. (RESERVED)

SUBCHAPTER 17. PLAN DOCUMENTS FOR GROUP CONTRACTS

8:38-17.1 Scope and applicability

- (a) This subchapter shall apply to all HMO health benefits plans that are not standard health benefits plans promulgated by the Small Employer Health Benefits Program Board of Directors and which are not otherwise subject to the Small Employer Health Benefits Program Act, N.J.S.A. 17B:27A-17 et seq., and rules promulgated thereunder, with respect to terms and conditions of contracts and certificates (evidences of coverage) issued to small employers, as that term is defined by the Small Employer Health Benefits Program Act.
- (b) This subchapter shall apply to all HMO health benefits plans that are not standard health benefits plans promulgated by the Individual Health Coverage Program Board of Directors or otherwise subject to the Individual Health Coverage Program Act, N.J.S.A. 17B:27A-2 et seq., and rules promulgated thereunder with respect to terms and conditions of the contract or policy forms issued on a nongroup basis under the Individual Health Coverage Program Act.

8:38-17.2 General requirements

- (a) The HMO shall provide a written contract to the contractholder and an evidence of coverage to each subscriber, which evidence of coverage may be incorporated into the member handbook required pursuant to N.J.A.C. 8:38- 9.1.
- 1. The contract, evidence of coverage and member handbook shall conform to the Life and Health Insurance Policy Simplification Act, N.J.S.A. 17B:17-17 et seq. as demonstrated by the submission of a readability certification with a Flesch score for each form.
- (b) All documents required to be delivered or issued for delivery in accordance with (a) above shall be delivered or issued for delivery no later than 30 days following the date of enrollment of the group, or notice to the HMO of enrollment of a subscriber within the group.
- (c) No plan document shall be delivered or issued for delivery unless the form thereof has been filed with the Department and the Department of Banking and Insurance, and approved, or deemed approved, by the Department of Banking and Insurance.

8:38-17.3 Terms and conditions for plan documents

- (a) Every plan document shall contain the following:
- 1. Information about the HMO and how to contact and obtain information from the HMO, including, but not limited to, the HMO's legal name, its trade name, and phone, fax and e-mail numbers by which consumers and members may contact the HMO, including at least one number that is a toll-free number for members:
 - 2. The eligibility requirements for the health benefits plan;
- 3. A specific description of benefits and services available within the service area under the health benefits plan, including emergency services, and out-of-area benefits and services;
- 4. A specific description of amounts that must be paid by members upon receipt of health care services, including copayments, deductibles, and coinsurance, as applicable, and with respect to POS contracts, an explanation of the member's obligation to pay charges for out-of-network services that exceed what the HMO determines are usual, customary and reasonable;
 - 5. A description of the grounds for termination of a member and group;
 - 6. A description of the claims procedures for members for out-of-network services;
- 7. A complete description of the HMO's method for resolving member complaints or grievances, and the process for appealing a utilization management decision, including all time frames applicable to the processes for making and resolving the complaint, grievance or appeal;
- 8. A description of continuation of coverage for those individuals who are in a health care facility at the time of termination of the group contract;
- 9. A description of how coverage under the health benefits plan may be continued pursuant to applicable Federal or State law (COBRA and/or N.J.S.A. 17B:27A-27) in the event of both member termination and group termination;

- A description of the extension of benefits for those members who become totally disabled;
 - 11. A description of the service area.

8:38-17.4 Specific standards for required provisions

- (a) With respect to information about the HMO, the name, address and telephone number of the HMO shall be included, with a telephone number by which members may contact the HMO without incurring toll charges.
- (b) With respect to eligibility requirements, the plan documents shall state what conditions must be met in order to enroll as a subscriber or a subscriber's dependent, the limiting age for subscribers and dependents, if any, including the effects of Medicare upon continued eligibility of the subscriber or dependent for some or all of the covered services under the health benefits plan, and a clear statement regarding the coverage of newborns.
 - 1. The statement regarding newborns shall be consistent with N.J.A.C. 8:38-3.2.
- 2. There shall be a provision regarding special enrollment periods for employees and dependents, consistent with the requirements of the Health Insurance Portability and Accountability Act, Pub. L. 104-191, and the laws of this State regarding group health insurance, N.J.S.A. 17B:27-54 et seq.
- 3. All other provisions regarding eligibility shall be consistent with Federal and State laws, including eligibility of children also eligible for Medicaid, and dependency established as a matter of court order.
- (c) With respect to the description of benefits and services, the descriptions shall be consistent with the rules in this chapter regarding required benefits and services, emergency services, and out-of-area services, and shall set forth any limitations and exclusions that may apply with respect to services and the receipt of services.
- 1. Statements regarding limitations and exclusions shall include any limitations or exclusions due to preexisting conditions, waiting periods or affiliation periods, or a member's refusal of treatment.
- 2. In no instance shall an HMO include statements in the plan documents requiring or suggesting that a member may only obtain emergency services through a participating or otherwise affiliated provider.
- (d) With respect to member termination, the provision shall not be inconsistent with N.J.A.C. 8:38-3.4, nor may the HMO cancel or nonrenew a member's coverage solely on the basis of the items set forth at N.J.A.C. 8:38-3.2(a).
- (e) With respect to the claims processing information, the information shall include, but not be limited to, the requirements for filing proper proof of loss, any time limit on the filing of claims or payment of claims, explanations of how disputed claims may be resolved, any restrictions on assignment of a claim, and whether a standard claim form is required to be used.
- (f) With respect to the continuation of coverage of a member when the member is admitted to the health care facility on the date that the group health benefits plan is terminated, the provision shall specify that the HMO shall continue to provide benefits for the member until the date of the member's discharge from the health care facility, or exhaustion of the member's benefits under the terms of the health benefits plan, whichever occurs first, and in no event shall the provisions be inconsistent with the standards of N.J.A.C. 11:2-13.
- (g) With respect to coordination of benefits, if the HMO will coordinate benefits under the health benefit plan, the HMO shall comply with N.J.A.C. 11:4-28; otherwise, the HMO shall include a statement that coverage under the health benefits plan shall be primary coverage for all members.
- (h) With respect to the extension of benefits for total disability, the provisions shall not be inconsistent with N.J.S.A. 17B:27-51.12.
- (i) With respect to the entire contract provision, the HMO shall include a statement that the contract, all applications and any amendments thereto constitute the entire agreement between the parties, and the HMO shall not include any portion of its charter, bylaws or other documents as part of the contract or plan document unless set forth in full in the contract or attached to it.
- (j) With respect to the term of the coverage, termination of the group contract and renewal, the HMO shall include a provision that specifies the date or occurrence upon which coverage becomes effective, the anniversary date of the contract, conditions upon which cancellation or termination may be

effected by the HMO, the contractholder and/or the subscriber, and the conditions for and any restrictions upon renewal.

- (k) With respect to the grace period, the HMO shall provide for a grace period of no less than 30 days for the payment of any premium other than the initial premium, during which time the coverage shall remain in effect.
- 1. The provision shall specify that the HMO shall remain liable for providing the services and benefits covered under the health benefits plan, the contractholder remains liable for payment of the required premium, and the members remain liable for any copayments, deductibles, coinsurance or other costs that may be applicable under the terms of the health benefits plan.
- 2. The provision shall specify that if the premium is not paid during the grace period, coverage is automatically terminated at the end of the grace period, effective as of the end of the grace period, and that the HMO shall provide notice of the effective date of the termination to the contractholder no more than 30 days following the effective date of the termination.
- (I) With respect to the conformity of law provision, the HMO shall provide that any portion of the contract that is not otherwise in conformity with the laws of this State, including but not limited to, N.J.S.A. 26:2J-1 et seq., 26:2S-1 et seq., and rules promulgated pursuant thereto, and 17B:27-49 et seq., as amended by P.L. 1997, c. 146, shall not be rendered invalid but shall be construed and applied as if it were in full compliance with the applicable laws and regulations of this State.

8:38-17.5 Standards for optional provisions

- (a) If an HMO intends to coordinate benefits under the health benefits plan, the plan documents shall include a statement specifying that coordination may occur, and an explanation of how coordination will be achieved.
- 1. Coordination of benefits shall be accomplished in accordance with N.J.A.C. 11:4-28, and the explanation of coordination of benefits shall not be inconsistent with those rules.
- 2. If an HMO fails to include a provision regarding coordination of benefits consistent with N.J.A.C. 11:4-28, the health benefits plan shall be primary coverage for all members.
- (b) If an HMO will allow reinstatement of the group health benefits plan, and/or coverage for a member, the plan documents shall include any terms and conditions for reinstatement.

8:38-17.6 Compliance

Forms of plan documents in effect on May 1, 2000 shall be deemed withdrawn on May 1, 2001 if not in compliance with this subchapter.

SUBCHAPTER 18. DRUG FORMULARIES

8:38-18.1 Development of formulary

- (a) A formulary provided pursuant to a health benefits plan issued by an HMO shall be developed by a pharmacy and therapeutics committee composed of health care professionals with recognized knowledge and expertise in clinically appropriate prescribing, dispensing and monitoring of outpatient drugs or drug use review, evaluation and intervention. The membership of the committee shall consist of at least two-thirds licensed and actively practicing physicians and pharmacists, and shall consist of at least one pharmacist. If the HMO contracts with a third party to develop the formulary, the HMO shall be responsible for guaranteeing that the third party complies with all requirements relating to formularies as set forth in this subchapter.
- (b) All drugs in a formulary shall be approved under the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.).
- (c) A formulary shall include more than one medication used to treat each covered disease state where more than one medication is available.
- (d) A medication may be excluded from a formulary only if, based on the compendia listed in N.J.A.C. 8:38-18.2(c)1, it does not have a significant clinically meaningful therapeutic advantage in terms of safety, effectiveness or clinical outcome of treatment for the specific condition for which the medication is intended over other medications included in the formulary, and there is a written explanation of the basis for the exclusion that is available to providers and covered persons upon request.

8:38-18.2 Nonformulary medications

- (a) Every health benefits plan issued by an HMO that provides benefits for formulary medications shall also provide benefits for nonformulary medications. Increased benefits may apply to formulary medications provided the difference between the total benefit value of formulary medication coverage and the total benefit value of nonformulary medication coverage does not exceed 30 percent. Compliance with this requirement shall be demonstrated by submitting to the Department of Banking and Insurance a completed Actuarial Justification of Benefit Differentials form (incorporated herein by reference as the Appendix to this subchapter).
- (b) The HMO shall establish an approval process to enable health care providers and covered persons to obtain coverage of nonformulary medications at the same level as formulary medications where the prescribing health care provider certifies the medical necessity of the medication.
 - (c) A nonformulary medication shall be considered medically necessary if:
- 1. It is approved under the Federal Food, Drug and Cosmetic Act (21 U.S.C. §§ 301 et seq.); or its use is supported by one or more citations included or approved for inclusion in the American Hospital Formulary Service Drug Information or the United States Pharmacopoeia--Drug Information, or it is recommended by a clinical study or review article in a major peer reviewed professional journal; and
- 2. The prescribing health care provider states that all formulary medications used to treat a disease state have been ineffective in the treatment of the covered person's disease or condition, or all such medications have caused or are reasonably expected to cause adverse or harmful reactions in the covered person.
- (d) The approval process for nonformulary medications shall provide that the HMO approve or deny the request by communicating such approval or denial to the prescribing health care provider by telephone or other telecommunication device within five business days of a request for prior authorization. Failure to approve or deny the request within five business days shall be deemed an approval of the request. Initial denials shall also be provided to the prescribing health care provider and covered person in writing within five business days of receipt of the request for approval of a nonformulary medication, and shall include the clinical reason for the denial. Such denials are appealable to the Independent Health Care Appeals Program in the Department of Health and Senior Services pursuant to N.J.S.A. 26:2S-11.
- (e) The HMO shall file with the Department of Health and Senior Services and the Department of Banking and Insurance a report summarizing all formulary appeals and their resolutions for the preceding year on forms prescribed by the Department of Health and Senior Services. Such report shall be included as a separate page with the HMO's annual report filed pursuant to N.J.S.A. 26:2J-9.

8:38-18.3 Distribution of formulary

- (a) The HMO shall publish and distribute, at least quarterly, either its current formulary or a list of nonformularies, to all network providers in electronic or paper form. Such list shall clearly indicate whether the medications included are formulary or nonformulary. Alternatively, the HMO may annually distribute new formularies or a list of nonformularies, and quarterly updates, to all network providers. Publication of a current formulary or list of nonformularies on the internet shall satisfy the requirements of this subsection.
- (b) The current formulary or list of nonformulary medications shall be provided by the HMO to covered persons and contractholders upon request.
- (c) The contract and evidence of coverage form shall disclose the existence of the formulary, describe the approval process to obtain coverage of nonformulary medications as formulary medications and describe the process to appeal a denial of a request for approval of a nonformulary medication, including the right to appeal to the Independent Health Care Appeals Program in the Department of Health and Senior Services pursuant to N.J.S.A. 26:2S-11. The contract and evidence of coverage form shall state that a copy of the formulary will be provided by the HMO to a covered person and contractholder upon request.

8:38-18.4 Operative date

- (a) This subchapter shall become operative on July 1, 2001.
- (b) All noncomplying HMO contract forms submitted for approval pursuant to N.J.A.C. 11:4-40 shall be deemed withdrawn effective July 1, 2001.

SUBCHAPTER 18. DRUG FORMULARIES APPENDIX

(14)/(1)

(15 in)-(15 oon) (16)

(15)

Benefit ratio

Benefit differential

Actuarial Justification of Benefit Differentials

Formulary Drug Benefit

			Use <u>Percent</u>	Formulary	Non Formulary
Number of Scrip	ots per	member per year			
	and	, ,			
G	eneric				
Co	omposit	e			
Ingredients cos	t includi	ing dispensing fees			
Br	and				
G	eneric				
Co	omposit	e			
Copays/Coinsu					
	and cop	-			
	eneric c				
	oinsurar				
	eductible				
	ut-of-po	cket limit (excl. ded)			
Calculation	(4)	0, ,, ,,			
	(1)	Starting claim cost F			
-	(2)	Adjustment for branc			
=	(3)	Adjustment for gene			
=	(4)	Adjustment claim co	st		
	(5)	Value of deductible	d = .d = 49=1 =		
X	(6)	Impact of 3x family of			
= (4) (7)	(7)	Adjusted value of de	eductible		
(4)-(7)	(8)	Adjusted claim cost			
X	(9)	Coinsurance			
=	(10)	Adjusted claim cost	Lond Honeld		
+	(11)	Impact of out-of-poc	ket iimit		
=	(12)	Adjusted claim cost			
(10) v (1 (10))	(13)	Formulary discount			
(12) x {1-(13)}	(14)	Net claim cost			

CHAPTER 38.	HEALTH MAINTENANCE ORGANIZATIONS APPENDIX (Reserved)	